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Standard Guidelines for Publication of Deep Brain Stimulation Studies in Parkinson's Disease (Guide4DBS-PD)

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Abstract

While the use of deep brain stimulation (DBS) for the treatment of neurological disorders has risen substantially over the last decade, it is often difficult to compare the results from different studies

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due to the lack of consistent reporting of key study parameters. We present guidelines to standardize the reporting of clinical studies of DBS for Parkinson's disease (PD). These guidelines provide a minimal set of required data elements to facilitate the interpretation and comparison of results across published clinical studies. The guidelines, summarized in the format of a checklist, may also have utility in the planning of clinical studies of DBS for PD as well as other neurological and psychiatric disorders.

Keywords

deep brain stimulation; publication guidelines; movement disorders; Parkinson's disease

The use of deep brain stimulation (DBS) for the treatment of neurological disorders has grown substantially over the last decade. DBS is considered a standard and accepted treatment for Parkinson's disease (PD),[1–5] essential tremor,[6–7] and dystonia.[8–11] In addition, DBS is being explored for a wide range of medically refractory neurological disorders including the tics associated with Tourette syndrome,[12,13] depression,[14,15] and obsessive-compulsive disorder.[16] There is also some evidence to suggest that DBS may also have utility in addiction,[17] stroke recovery,[18] headache,[19,20] and minimally conscious state.[21] New applications continue to develop as the methodology evolves, the technology improves and we gain a better understanding of the pathophysiology of these disorders and the mechanism of action of DBS.

In spite of this rapid expansion of clinical indications for DBS, there remain significant questions concerning how to optimally administer DBS for the treatment of PD. While there have been numerous clinical investigations, the results from these studies are often difficult and sometimes impossible to compare due to the lack of standardized methods of assessment and reporting. For example, the time of assessment relative to implantation and programming is variable, as is the duration of time with the stimulation turned off or on prior to performing the outcome assessments. In addition, there is a lack of consistency in the reported outcome measures across studies. Lead locations and the methods of verification are rarely reported other than to state the standard atlas coordinates or note that the lead was correctly positioned. A non-standardized approach to study and report the effects of DBS makes it difficult to determine the source of differences both within and between studies and to compare outcomes across studies.

One approach for dealing with this problem is the development of guidelines for reporting clinical studies of DBS. Driven by a consensus from within respective scientific fields, guidelines provide a minimal set of required data elements to facilitate interpretation across published clinical studies. If adopted, the guidelines can not only aid in the systematic peer-review of manuscripts describing results from clinical studies, but also can have utility in the design of a clinical study. Examples of such guidelines include Consolidated Standards of Reporting Trials (CONSORT),[22] Standards for Reporting Studies of Diagnostic Accuracy (STARD),[23] Transparent Reporting of Evaluations with Nonrandomized Designs (TREND),[24] and Guidelines for Neuro-Oncology (GNOSIS).[25,26]

In this article, we present guidelines for reporting results from clinical DBS studies in PD (Guide4DBS-PD). Our primary goal is to provide a framework for data presentation that will facilitate the comparison and interpretation of findings across clinical studies. Secondarily, we hope these guidelines will assist the growing international DBS research community in designing clinical studies as well as the review of manuscripts submitted for publication. Similar to GNOSIS,[25,26] our guidelines are in the format of a checklist to enhance implementation and use. It is important to acknowledge that these guidelines identify only a minimal, rather than exhaustive, set of parameters that are presently considered vital for data sharing across DBS clinical studies in movement disorders. It is likely that these guidelines will require periodic updates as our understanding of how DBS treats motor dysfunction in PD grows and new technologies for stimulation and imaging emerge.

METHODS

With the support of the National Institute of Neurological Disorders and Stroke at the National Institutes of Health, a team of DBS experts from Canada, Europe, and the United States were brought together to develop a set of reporting guidelines that are considered the minimum necessary to allow for meaningful comparisons of DBS studies. Drawing upon their expertise, each member drafted a minimal set of standards within a particular area of DBS study methodology and results. The areas addressed were: (1) preoperative information: patient selection and evaluation, (2) intraoperative information: targeting, lead placement, and lead verification, (3) postoperative information: programming, outcome reporting, complications and adverse events (AEs).

RESULTS

Preoperative Information: Patient Selection and Evaluation

It is important that manuscripts describing the results of DBS for PD provide standardized information about the patients involved in the study. This information should include basic demographic data and information on disease state, how the patients were selected for treatment including specific indications for surgery and exclusion criteria, and finally, how and when the status of the disease was evaluated preoperatively. Section 1 of the checklist identifies the preoperative factors that should be included in any report of DBS outcomes in PD patients (Table 1). These items will be discussed briefly below.

There should be some statement that the patients fulfilled specific diagnostic criteria for PD with an appropriate citation, for example the UK Brain Bank Criteria.[27] The age of the patient and duration of disease should be provided. Information about current dopaminergic therapy is generally given in the form of “levodopa dosage equivalents.”[28] Either the details of this calculation or appropriate citation should be provided. Where appropriate, more information on the dosages of subcategories of drugs should be included (e.g., if a specific behavioral or neuropsychiatric problem were the focus of the study then providing information on dosages of dopamine agonist may be important in the interpretation of the outcomes). Preoperative and postoperative PD evaluations have been considered in detail in the literature[29–31] and will not be discussed at length. In the preoperative state, it should be

noted if the off-medication ("practically defined off") and on-medication Unified Parkinson's Disease Rating Scale (UPDRS)[32] evaluations were completed, who performed these tests and whether or not the investigators were certified in the use of the scale. The dosage of dopaminergic medication used for the on-medication assessments should be provided with specific information as to how this was calculated. Given the variability in the response and the fact that dyskinesia is reported in the UPDRS, there was less consensus in this group of experts regarding the application of a specific dyskinesia rating scale. Since the consensus meeting, the Unified Dyskinesia Rating Scale (UDRS) has been developed by the Movement Disorder Society.[33,34] Finally, many studies are now evaluating outcomes using quality of life and other non-motor assessments in addition to the usual PD motor function scales. Although these are not mandatory they are recommended and if included, a disease-specific scale such as the PDQ-39[35] should be used with or without a generic quality of life assessment scale. Studies examining a specific outcome such as anxiety, depression, caregiver burden, social impact, sleep, etc. should include a description of the methods of assessment and of any scales used as part of the assessment.

The indications for DBS for PD are evolving. A specific statement of the indication(s) for surgery should be provided. Traditionally, DBS has been provided for L-dopa-responsive patients disabled by motor complications. As a minimum, the UPDRS scores on- and off-medication should be reported. Part IV of the UPDRS regarding duration and severity of off-time and dyskinesia should also be reported. Diaries could also be utilized, however it is recognized that the quality of these data varies considerably and cannot therefore be considered mandatory.[36] If these data are reported and particularly if used as a primary endpoint, a statement should be made as to how patients were trained in the use of the diaries prior to the study and how quality assurance was maintained throughout the study.

In studies where the indications for surgery differ from traditional indications, the methods for selecting patients and evaluating outcomes need to be detailed. For example, L-dopa-resistant symptoms are of special interest both for currently established targets and particularly for novel targets such as the pedunculopontine nucleus (PPN). Relevant subscores of the UPDRS should be included to address the respective issue.

Documentation of further preoperative screening should include imaging, neuropsychological testing, and neuropsychiatric assessment. It is generally agreed that all patients should undergo brain MRI assessment in advance of the surgery to exclude additional pathology that might contraindicate surgery, compromise outcome or suggest an alternative cause of parkinsonism such as tumor or vascular insult. A statement regarding the neuropsychological and neuropsychiatric assessments used should be provided.[37] There are many appropriate alternatives, so it was not felt that a single uniform approach to this screening is required.[38]

Intraoperative Information: Targeting and Lead Location

General information about the surgical procedure should be reported including the targeted brain structure and the planned procedures such as unilateral, bilateral simultaneous, or bilateral staged placement with timing between placements. In addition, the timing of the implantable pulse generator (IPG) placement with respect to lead placement should be

noted. The basic intraoperative information that should be included in all DBS reports is listed in Table 1. These include the target, planning methods and coordinates used, use of anesthesia, whether anti-parkinsonian medication was used intraoperatively, whether the frame or frameless technique was used, targeting technique (e.g., direct or indirect targeting) and whether microelectrode mapping and macrostimulation were used and how they were used, method of verification of lead location, and statement of DBS lead type and IPG used.

Regarding the planning methods used to determine the appropriate placement of the leads, it should be noted whether ventriculography, MRI, CT, or image fusion techniques were used and the planning station or software used to identify the target should be included. Most importantly, how the final location of the lead was ascertained should be discussed. It is not adequate to state lead placement was confirmed by MRI. The criteria used to determine the accuracy of such placement should be described.

As a minimal requirement, intraoperative analgesia should be clearly indicated. Specifically, the manuscript should indicate whether local anesthetics alone, local anesthetics in combination with IV supplements, or general anesthesia with endotracheal intubation or laryngeal mask anesthesia were used.[39] If electrophysiology was performed under general anesthesia, the type of general anesthesia should be clearly indicated as this may or may not affect the electrophysiology.[40,41] The authors should also indicate the status of anti-parkinsonian medications during surgery. In the majority of cases, these medications are withheld; however, in some cases their use may be necessary and may impact the identification of target structures and final lead position.

Although the information in the following two paragraphs is not considered mandatory, it can be helpful for others performing these types of surgeries to interpret AE data and understand the potential reasons for improper lead placements when they occur. As such, the type of frame, position of the head during surgery, type of opening, and the method for CSF management are useful to include in the surgical methodology. Whether supine or semi-seated, the type of entry (burr hole or twist drill hole) and any sealant used to manage CSF loss also provide valuable information. The rationale for this is based on the fact that there can be significant intracranial shifts following CSF leakage.[42–44] The type of frame and imaging should allow for standardization as to accuracy and application error in the prelude to surgery.[45–47]

Image guidance techniques are increasingly being used not only for target identification but also for intraoperative trajectory planning. As a minimum requirement, the type of platform and software program used should be clearly indicated. The vast majority of centers couple imaging with electrophysiology in determining final target location. It is essential that the type of electrophysiological monitoring be reported. Whether impedance monitoring, semi-microelectrode, microelectrode recordings or macrostimulation, the details of the physiological technique, and strategy used to identify the target and determine the site of placement within the target should be clearly indicated. An ongoing debate regarding the use of electrophysiological monitoring is the discrepancy observed between image-based targeting and the final target location as determined by electrophysiology.[48–50] Therefore,

there is a need to document the various methods used to guide lead placement to allow a rational evaluation of safety and effectiveness.

If microelectrode recordings are used, it is important to indicate how this information is assembled and integrated. The number of passes (mean and range) used to identify the target as well as the criteria used for mapping or identification of the target should be clearly indicated. It is important to discuss whether the information was simply used for confirmation of anatomy or if an electrophysiological map was created. If mapping and/or macrostimulation through the DBS lead was performed, the criteria used for determining that sufficient information was obtained to place the lead should be included. The atlases used and the use of any additional special electrophysiological techniques such as evoked potentials as well as additional intraoperative imaging techniques, fluoroscopy or tomography during mapping should be clearly indicated.

The type of lead and method of verification of final lead placement are minimal requirements that need to be documented. While many report their final location in terms of *x*, *y*, and *z* coordinates in relation to the midcommissural point, biologic variability in patients requires one to provide more substantive criteria upon which to determine location. While there are no established criteria at this time for determining lead location, at a minimum, each author should provide the means by which they assessed lead location.[51,52] Concerns about MRI have forced some centers to stop or modify the postoperative imaging. Many centers use direct localization of the leads for the postoperative imaging while others fuse preoperative and postoperative imaging. The authors should document the details of the procedure. In addition, macrostimulation through the lead or through probe as well as the parameters used for stimulation are helpful as is the type of probe used. Finally, any intraoperative confirmation of the lead location such as fluoroscopy, x-ray, or even tomography should be indicated. Imaging is essential for fully documenting symptomatic and non-symptomatic complications, i.e., hemorrhages, infarcts, lead misplacement, etc. Thus, CT or MRI imaging postoperatively is a minimal requirement.

Postoperative Information: Programming, Outcome Data, and Adverse Events

Programming Considerations—Several variables related to programming DBS devices following implantation should be reported in all DBS studies. These are critically important to the study as they have a marked impact on outcome. Poor programming can result in a suboptimal outcome, which may be misinterpreted as being related to the preoperative diagnosis or location of the lead rather than being attributed to the final programming parameters and strategy selected. Therefore, it is critical that the following basic information about programming be included.

At a minimum, the stimulation parameters (choice of contacts and which ones are anodal or cathodal, pulse width, voltage, stimulation frequency, and whether monopolar or bipolar) at the time of assessment should be stated as well as how long the patient was at these settings before outcome assessments were completed. When turning the patients' IPG OFF or ON or when making changes to antiparkinsonian medications, it is critically important to note how long the patients were OFF stimulation or ON stimulation prior to the time of the assessment. A table listing the programming parameters should be included. Impedance is

important to report as it may significantly influence the amount of current spread but is not mandatory. Knowledge of the impedance provides important information when comparing stimulation parameters across studies. In addition to the above, the following items while not mandatory are helpful to include in a DBS manuscript and include the number of programming changes required to get to the "optimal" settings and the method used to program the patient including how settings were selected, programming strategy and duration of time or number of visits to optimize the patient.

Outcome Reporting—As a general quality standard most journals request the CONSORT-recommendations,[53] which also apply for surgery studies. Moreover, the importance of standardization in performing and reporting of postoperative assessments cannot be overstated as this is critical to provide a meaningful comparison of outcomes across studies of DBS. While it is not practical to expect all studies can provide the detailed assessment described below, the assessments that are performed should be performed and reported in a standardized fashion. Mandatory information should include the time of assessments relative to implantation, the medications at the time of assessment and if possible the time of the last medication change relative to the assessment, stimulation parameters at the time of assessment and if possible the time of the last programming change. This information should be provided as it relates to neuropsychological assessment and UPDRS scores. It would be optimal to have UPDRS motor scores (Part III) under all four conditions (meds off/stim off, meds off/ stim on, meds on/stim off, meds on/stim on) at standard time points following surgery. Most studies report UPDRS motor scores in the meds off/stim on condition in comparison to the meds off/stim off condition. This comparison provides a good, reasonably objective assessment of the effect of stimulation on parkinsonian motor signs. Therefore, it is strongly preferable that motor assessments be conducted and data reported from these testing conditions in studies of DBS; however, many patients over time do not want to undergo the off/off evaluation, and as such we would argue that at a minimum the condition under which the assessments are performed be clearly defined and reported. In addition, UPDRS Part IV changes in duration of off-time and dyskinesia should be reported. As discussed in the preoperative assessment section, it is strongly encouraged that a postoperative assessment of quality of life, either disease specific or a general assessment be included. Section 3 of Table 1 contains the suggested minimum reporting criteria of postoperative outcome data.

Intraoperative and Postoperative Complications and Adverse Events—Reporting of complications is heterogeneous across centers. Complications are not considered serious by some and not reported, others report per patient and yet others per lead. There is a large degree of variance in recognition, acceptance, and reporting of complications in the literature.[54] Reporting of the incidence and type of AEs are critically important for any study and should be included in all studies of DBS for PD to allow for centers to learn from the experience of others and to be able to assess the potential risks associated with these procedures and their effect on outcome.

The number of cases is important, but also the number of aborted cases is a minimum requirement. The reason for aborting the case should be indicated, i.e., concern regarding

patient's respiratory status or possible intracranial hemorrhage, etc. A description of the timing such as aborting before the first lead was placed or aborting after the first lead was placed, or aborting before the second lead was placed would be helpful. Replacements and repositioning of leads, IPGs or extension wires should be discussed including the reason for the additional surgical procedure and the timing with respect to the initial placement. Complications and AEs should be reported, both per patient and per implanted lead. For all complications, the timing with respect to the implant, the severity of the AE, action taken, and the status of the AE (i.e., resolved, transient, permanent) at the time of the report should be included. Surgical complications are generally defined as those occurring within 30 days of the surgical procedure. The minimum surgical complications should include aborted procedures, replacement or repositioning of hardware, location and type of hemorrhage, location and type of infection, seizures, headache, confusion, and other neurological or neuropsychiatric changes. Any additional AEs possibly related to the surgery should also be reported. Complications related to the breakage or malfunction of the hardware should be reported including erosion, fracture, migration, shocking sensations, open or short circuits, lack of effect, etc. Ongoing AEs related to the stimulation should also be reported including paresthesia, dysarthria, gait, or balance changes, etc.

CONCLUSIONS

We have presented a set of minimal reporting guidelines for the application of DBS in the treatment of PD (Guide4DBS-PD). These guidelines were developed to improve our ability to understand the reasons for differences in outcomes across studies, and help us to identify those PD patients who may best benefit from DBS and characterize the critical variables in determining outcome. As such, we believe these guidelines if implemented can improve the practice of DBS for PD and serve as a template for the development of future clinical trials for PD as well as other neurological disorders.

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TABLE 1

Guide4DBS-PD checklist of minimum guidelines for DBS reports

Preoperative information: patient selection and evaluation

- ☐ Diagnostic criteria (e.g., UK Brain Bank criteria)
- ☐ Age at time of surgery
- ☐ Disease duration at time of surgery
- ☐ Current medication status (e.g., levodopa equivalents with formula, other relevant medications)
- ☐ Indication(s) for surgery (e.g., motor fluctuations, dyskinesia, tremor, other)
- ☐ Inclusion/exclusion criteria used for screening surgical candidates
- ☐ Details of UPDRS ON/OFF assessment (e.g., practically defined ON and OFF, difference between ON and OFF)
- ☐ UPDRS Part IV—duration of OFF time and duration of dyskinesia
- ☐ Description of additional assessments if applicable
- ☐ MRI findings (general statement if normal; description of abnormal)
- ☐ Brief description of neuropsychological and neuropsychiatric assessments

Intraoperative information: targeting and lead location

- ☐ Target (e.g., STN, GPi, etc.) and procedure (unilateral, bilateral simultaneous, bilateral staged)
- ☐ Target planning method (e.g., direct or indirect, atlas, planning platform, software, imaging, ventriculography)
- ☐ Anesthesia—type, timing (throughout procedure or intermittent)
- ☐ Frame type or frameless procedure
- ☐ Type of opening (burr hole, twist drill hole)
- ☐ Method of target localization (e.g., image guidance platform, software, electrophysiology, fluoroscopy)
- ☐ If microelectrode recording number of passes and criteria for mapping
- ☐ Method of lead location verification (e.g., post-op imaging, fluoroscopy, comparison to target)
- ☐ Lead and IPG models used

Postoperative information: programming, outcome data and adverse events

- ☐ Number of cases including total operated and number included in report
- ☐ Number of cases not included and reason not reported or reason for dropout during duration of study
- ☐ Time of assessment relative to time of implantation
- ☐ Levodopa equivalents or other relevant medications
- ☐ Stimulation parameters (amplitude, frequency, pulse width, choice of contacts) and impedance at time of assessment
- ☐ If stimulation turned ON and OFF, duration of time in each condition at time of assessment
- ☐ Neuropsychological assessment
- ☐ UPDRS—indicate subscales and status of medication and stimulation
- ☐ UPDRS Part IV—duration of off-time and dyskinesia
- ☐ Complications and adverse events reported per patient and per implant
- ☐ Aborted procedures—number, reason
- ☐ Hardware replacements or repositioning—reason, timing with respect to initial procedure
- ☐ Surgical complications—severity, action taken, outcome, location where applicable (infection, hemorrhage)
- ☐ Hardware complications—description, severity, action taken, outcome
- ☐ Stimulation adverse effects—description, action taken, outcome