



September 1, 2014

Newsletter #11

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Status update

- NEW! DBS for PD 1074 entries added in August (3 data extracted waiting for finalized category list)
- SCS 1632 entries (18 added in August update), 73 data extraction completed
- DRG 6 entries, 5 data extraction completed
- DBS for OCD 82 entries (4 added in August update)
- 114 subscribers (8 added in August; thank you for continuing to spread the word about WIKISTIM!)
- NEW! WIKISTIM now has discrete searchable sections for SCS and DBS (after the first search is conducted in either section, a user also has the option to "search all" entries)
- NEWS can now be accessed on the home page without registration or log in
- Support from a new source will keep WIKISTIM "live" through December 2014

DBS for Parkinson's entries

In August, we added 1074 entries with primary data for DBS for PD (972 involving human subjects, 49 involving laboratory animals, 36 modeling studies, and 17 technical studies). We included 1) entries from a PUBMED search of "deep brain stimulation" and "Parkinson" for the past 5 years, 2) entries from our DBS collection, and 3) all of the RCTs that we could identify. We culled the result of our search to include only reports with primary data (clinical, experimental, and modeling studies). Unlike our list for OCD, our curated list for PD is not comprehensive, but it is exclusive. We intend to augment this list each month and welcome suggestions of papers to include.

DBS for Parkinson's data category development

We reviewed pertinent literature and drafted a list of 174 data categories for DBS. A neurosurgeon prominent in the field of DBS kindly reviewed this draft list and suggested improvements and additional resources. Interested readers can find the draft category list appended to this newsletter. We obviously need to devise some additional outcome measures that will cover indications beyond PD. We will be working on the list in September and would appreciate any input. Please feel free to email us with your suggestions about any aspect of this list of data categories. Nothing on WIKISTIM is written in stone, of course, but it behooves us to do the best job we can before we upload the data categories for DBS in September.

September plans

- Upload DBS data category list
- Quality control (e.g., updating our internal links in light of the structural changes we made in August, rechecking the search engine functionality, updating search synonyms for accented names, updating epubs, checking the rendering of recently added citations, etc.)
- Submit one or two abstracts to NANS 2014
- Submit a manuscript describing WIKISTIM to Neuromodulation
- Our website developer is incorporating the capability for a user to create a table from a checked selection of entries
- Add new sections (DRG, PNS, TENS, GES, etc.)
- Our website developer is creating the ability to sort the list of papers by “date citation added” and “date data extraction completed,” so that users can easily check “what’s new”
- Complete additional datasheets (towards our goal of 500 in 2014) and continue to seek feedback from authors
- Update SCS, DRG, and DBS (for OCD and for PD) citations

Ongoing goals

- Create links from WIKISTIM data fields (e.g., “migration”) back to the appropriate pages in the “Practice Parameters for the Use of Spinal Cord Stimulation for Neuropathic Pain” (see neuromodfound.org) and update those entries
- Improve and safe-guard the specificity and sensitivity of the search results as we expand in scope
- Increase the number of registered users by increasing awareness of WIKISTIM
- Identify authors and researchers who will submit datasheets for WIKISTIM

Frequently-asked questions

As it is currently configured, is WIKISTIM conducive to collaboration or sharing of information among clinicians, scientists, and engineers?

Collaboration and sharing of information among clinicians, scientists, engineers, and others is WIKISTIM’s raison d’être. Thus, WIKISTIM is configured to allow everyone to submit data, download datasheets, submit suggestions, and communicate via the forum.

Will patients find WIKISTIM helpful?

It would be easy, but presumptuous, to surmise that WIKISTIM is of interest only to professionals; we all know that patients use the Internet as a source of health information. WIKISTIM provides scientific information pertinent to patients in a format that many will find helpful. We expect that patients will tell their doctors, “I found this on WIKISTIM.” Furthermore, our companion website (neuromodfound.org), which contains a series of questions and answers about the use of SCS for chronic neuropathic pain, is patient-friendly.

Registration for WIKISTIM asks for degrees and institution names. Is this required?

The degree field is required, but registrants can and have entered free text. Some actual examples are: “Professor Emeritus, Medicine and Surgery,” “Psychology Physiotherapy,” “Research,” “Student,” “Engineer,” and “Biomedical Engineering.” These are, obviously, not “degrees.” We ran a test registration and found that “High School” was accepted in the degree field. Institution is not required. As noted above, visitors to WIKISTIM no longer have to register to look at the NEWS.

Why do you collect degree/institution data from your registrants?

We believe it is important that we understand the range of backgrounds of our registrants so that we can be certain we are offering a service that will lead to broad collaboration. For example, our first 110 registrants include those with the following degrees: AAS (1), BS/BA (9), BSME/MBA (3), JD (1), MA (4), MBA (12), MS (17), MS/MBA (2), PhD (21) MD/PhD (8), MD (18). MD/MPH (2), PharmD (1), other (11).

WIKISTIM includes some engineering articles, do you plan to include all that are of relevance to neuromodulation?

We plan to include all articles in all fields that are of relevance to neuromodulation. We began with the field that we know best, SCS, and we have included all of the engineering articles in that field that we know of; however, whereas we believe we have been exhaustive on the clinical side, we can’t be as certain on the engineering side, and we’d be delighted to work with an engineer to identify entries for SCS and other sections. Because it is web-based, WIKISTIM has no limits on its growth.

What constitutes a WIKISTIM section, and what is needed to create a new section of WIKISTIM?

Our sections reflect the various stimulation targets (SCS, DBS, DRG, PNS, TENS, etc.). To create a new section before we can get to it ourselves, we simply need a volunteer to work with us to identify a list of potential entries and to devise a list of data categories.

How does the range of search parameters on WIKISTIM compare with that available on PUBMED?

WIKISTIM uses a customized Google search. One can search ANYTHING with this search engine. Our “range of search parameters” is not limited, as is PUBMED's. WIKISTIM does have “data categories,” but searches are not limited to these categories. Unlike PUBMED where, for example, a search for “SCS” and “infection” will only yield those articles that have “infection” in the title or in the abstract, an identical search on WIKISTIM will yield articles with “infection” in the title and all articles in which the data category “infection” has an active (i.e., filled in) field.

In addition, unlike PUBMED, where a search yields a great deal of “noise,” the searchable papers on WIKISTIM have been curated so that the list includes only those pertinent to the subject at hand. This will save researchers a great deal of time and makes WIKISTIM valuable even as we are increasing the breadth and depth of the information available.

Does WIKISTIM include articles from journals that are not included in PUBMED?

WIKISTIM already includes 28 SCS articles (including book chapters and abstracts) from sources (including journals) that are not included in PUBMED. Inclusion in PUBMED is not a criterion for inclusion in WIKISTIM.

The logistical needs of WIKISTIM are substantial and rely heavily on the services of volunteers, much like Wikipedia. How will you attract volunteers?

We are pursuing a number of ways to attract volunteers. For example, the WIKISTIM datasheets are useful as a starting point for authors as they plan studies, prepare study reports, and review the literature. We anticipate that authors who prepare tables and do meta-analyses will use our datasheets and share the results with us. We further expect that these authors will abstract their own work into WIKISTIM data sheets and submit the results to us, so as to facilitate access and citation by others. This has already happened for a number of papers. Peer reviewers will also find these datasheets useful as a checklist. We hope that eventually journals will use WIKISTIM data fields as part of the submission and review process.

How will the WIKISTIM data entries be reviewed and edited?

One of the strengths of WIKISTIM is that this review can be done by anyone at any time, and corrections can be incorporated easily. Furthermore, Ms. Shipley comes to this task having written approximately 6,000 abstracts in the 1990s for the Population Information Program of the Center for Communication Programs at the Johns Hopkins University School of Public Health and with decades of experience in medical/scientific editing. To date, she has reviewed and edited all of the submissions and expects that others will review her work. WIKISTIM entries must be succinct and accurate, and the dictates of copyright law must be observed.

What is the added value for users of WIKISTIM vis-à-vis PUBMED and other databases?

What WIKISTIM offers, even in its embryonic state, is a curated list of papers, which means that WIKISTIM points to specific papers that might have otherwise taken a great of time to locate or might even been missed. For those papers that are listed in PUBMED, WIKISTIM users can link to the PUBMED abstracts (available for most entries) and then use the journal links on PUBMED to access the full-text papers. In the future, WIKISTIM might include links to the journals.

The WIKISTIM entries for which data abstraction has been completed provide the only access to these data in a format that facilitates rapid analysis and comparison, and the WIKISTIM data abstraction scheme yields much more information than will be found in a PUBMED abstract. WIKISTIM content will not be limited, as are meta-analyses and literature reviews, by date of publication, by the search terms the authors chose, or by the research question they asked. WIKISTIM will allow its users to ask their own questions and conduct up-to-the minute literature searches.

How you can help

- Support WIKISTIM with a tax-deductible donation to The Neuromodulation Foundation, Inc., a nonprofit 501(c)(3) organization. Our address appears below; please contact janeshipley@gmail.com with questions about donations.
- Spread the word (see below)
- Submit extracted data
- Notify us about any reports we might have missed for SCS and DBS/OCD or reports you would like to see added for DBS/PD
- Suggest improvements to the SCS data categories
- Review and suggest improvement to the draft DBS data categories appended below

Points you can make about WIKISTIM

Who will use WIKISTIM? Everyone in our field!

- Authors who write a series of papers can use WIKISTIM to confirm that data reported in a new paper are congruent with data reported in a prior paper. Over the years we have seen several cases of data discrepancy. WIKISTIM should help reduce this
- Busy clinicians who need answers to clinical questions or literature support for reimbursement
- Representatives of industry who are seeking regulatory approval or need comparative data for approved devices
- Researchers who want to determine research needs, review background information, prepare evidence tables, etc.
- Authors working on scientific publications who could profitably search WIKISTIM and, if they are writing a protocol or research report, could use the WIKISTIM data category template as an outline for their work (and could then submit the completed datasheet to us as soon as their report is accepted for publication, expediting entry and facilitating readership and citation)
- Authors and readers who wish to query and correct inconsistencies in published scientific papers
- Critical thinkers who want to discuss published reports without the typical space and time limitations of Letters to the Editor
- Investors and other interested lay people who are exploring neuromodulation therapy
- Regulatory agencies and third-party payers who need a basis for decision-making

Features of WIKISTIM

- Subscription remains free
- Published neuromodulation data abstracted and categorized
- Custom Google search engine
- Users download datasheets and can perform their own meta-analyses
- Users submit data from published papers
- Discussion of papers unlimited by time and space
- Links to PUBMED abstracts and to SCS Practice Parameters (neuromodfound.org)
- Includes citations that are not listed on PUBMED

Goals of WIKISTIM

- Improved patient care
- Support for reimbursement
- Facilitated regulatory submissions
- Improved quality of published reports
- Inspiration for research and innovation
- Increased communication that will extend the useful life of published reports

Disclosure

WIKISTIM includes citations of studies of the use of neuromodulation therapies for indications that are or might be considered off-label or experimental in the United States.

Thank you for your continued interest in WIKISTIM!

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APPENDIX: DRAFT DBS DATA CATEGORIES

STUDY DESCRIPTION

Study design

Study question

Population assessed (humans, rats, etc.)

Model used if experimental study (6-OHDA rat, MPTP primate, paraquat rodent, rotenone rodent)

Study dates

Follow-up duration
Follow-up intervals
Third-party follow-up
Other efforts to reduce bias
Patient protection measures
Outcome measures
Primary outcome
Secondary outcomes
Definition of success
Statistical significance
Statistical analyses performed

DBS PATIENT SELECTION

Inclusion criteria, including diagnostic criteria (UK Brain Bank criteria, Unified Parkinson's Disease Rating Scale scores, especially the motor score with and without drugs)

Exclusion criteria, including age cut-off (dementia, other serious co-morbidities or abnormalities)

DBS INDICATIONS

Parkinson's disease (breakdown if appropriate for tremor, bradykinesia, gait dysfunction, atypical)

Tremor

Dystonia

Tardive dyskinesia

Tourette's syndrome

OCD

Depression

Eating disorder (obesity, anorexia)

Addiction

Alzheimer's

Pain (yes or no; number of patients)

Pain (location; etiology)

Other

DEMOGRAPHICS

Sex (male/female)

Mean age (years +/- SD or range)

Race

Socioeconomic status

Years of education

PREOPERATIVE HISTORY, ASSESSMENTS, AND STATUS

Psych evaluations performed (See Lang 2006 Tables 1 and 2)

Medication

Status OFF medication

Status ON medication

Psychiatric history and status

Cognitive status (including verbal fluency)

Tremor status

Dyskinesia status

Other comorbid conditions

Disease duration

Diagnostic rating scores

PREIMPLANT CONSIDERATIONS

Assessment-to-implant interval

Period of withdrawal of medication

Method of medication withdrawal

Imaging type and result

Software used for co-registration of CT, MRI results

Target planning method (direct, indirect, combined; atlas, planning platform)

Frameless system type (if used)

Trajectory planning method (to avoid vasculature)

DBS SYSTEM IMPLANTATION

Number implanted

Aborted procedures (number, reason)

Frame type and manufacturer (if used)

Imaging type

Unilateral, bilateral simultaneous, or bilateral staged procedure

Target (subthalamic nucleus, global pallidus internus, ventral intermediate nucleus)

Method of intraoperative target localization (e.g., interventional MRI)

Anesthesia—type, delivery (continuous or intermittent)

Method of target verification (microelectrode, semimicroelectrode, macroelectrode, macrostimulation)

Type of recording microelectrode (if used)

Microelectrode mapping strategy (single or multiple pass, if used)

Type(s) of implanted electrode(s)

Electrode manufacturer

Method of securing electrode

Duration of electrode implantation procedure

Risk reduction during electrode implantation

Complications during electrode implantation (incidence, therapeutic intervention, outcomes)

Type of IPG

IPG manufacturer

Timing of IPG implantation

Location(s) of IPG(s)

Duration of IPG implantation procedure

Risk reduction during IPG implantation

Complications during IPG implantation (incidence, therapeutic intervention, outcomes)

POSTOPERATIVE ISSUES

Electrode location verification method

Imaging to rule out intracranial hemorrhage

Removal of fiducial markers (if used)

Timing of initiation of stimulation

Stimulation programming methods

Amplitude (volts)

Frequency (Hz)

Pulse width (micro seconds)

Contacts activated

Length of hospitalization

Pain relief therapy

Medication withdrawal strategy

Incidence and type of transient neuropsychiatric symptoms (e.g., confusion, apathy, depression, hypomania, suicide ideation)

STUDY OUTCOMES

Number in study

Number followed

Number lost to follow-up (and reason)

Number died

Complications (total, per patient, and per implant)

Rate of success if defined

Data presented disaggregated and summarized?

Outcomes reported as function of time?

Outcomes broken down by indication?

Answer to study question

Implication of study results

DBS OUTCOMES

Age differences in outcome
Sex differences in outcome
DBS OFF and MED OFF
DBS ON and MED OFF
DBS ON and MED ON
DBS OFF and MED ON
Change in health care use, including post-implant medication (levodopa equivalents with formula)
Change in dyskinesia
Change in dystonia
Change in motor function (tremor, bradykinesia, rigidity, etc.)
Change in activities of daily life
Change in quality of life
Change in sleep
Patient satisfaction or impression of change
Change in care-giver burden
Physician-reported clinical benefits
Latency and persistence of therapeutic effect
Employment status/return to work
Cost effectiveness

BEHAVIORAL AND PSYCH OUTCOMES (for complications, note severity, time to event, therapeutic intervention, final outcomes)

Duration of stimulation ON vs. OFF at assessment
Cognitive function (verbal fluency, dysarthria, confusion)
Emotional depression/mood
Apathy
Anxiety
Hypomania/mania
Response inhibition/Impulsivity
Pseudobulbar affect
OCD symptoms
Eating disorders
Addictive behavior
Inappropriate medication use
Psychosis (e.g., hallucinations, delirium)
Suicidal ideation and attempts (successful/unsuccessful)

DBS BIOLOGICAL COMPLICATIONS (note severity, time to event, therapeutic intervention, final outcomes)

CSF leak
Infection (location)
Hemorrhage (location)
Hematoma (location)
Venous air embolus
Seroma/granuloma
Skin erosion or wound dehiscence
Allergic or foreign body reaction
Surgical site pain (location)
Headache
Stroke
Neurological complications (abnormal muscle contractions, numbness, seizure, speech problems, dizziness, lightheadedness, weakness, paresis, impaired movement/coordination)
Other biological complication (visual field defect, temporary hemiballismus, buzzing sound)

DBS DEVICE COMPLICATIONS (note severity, time to event, intervention, outcomes)

Impedance
Electrode migration or malposition
Electrode failure or breakage

Lead or extension wire fracture or malconnection
Generator failure
Generator migration
Connector repositioned
Premature battery depletion
Device interaction (including MRI limitations)
Other hardware failure (including that which creates impedance)

DBS STIMULATION SIDE EFFECTS (intervention, outcome)

Extraneous paresthesia
Over, under, or intermittent stimulation
Uncomfortable/painful stimulation, including shocks

FACILITY AND STAFF

Physician training (note certification in use of assessment scales)
Physician experience
Facility location