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Capstone Scholarly Project

Gap in Patient Expectations of Deep Brain Stimulation for the Treatment of Parkinson's Disease

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4-28-15

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Abstract

Purpose: This project studied a specific group of patients with Parkinson's disease to: determine if they were asked to verbalize expectations of DBS pre-operatively; determine if patient expectations were met post-operatively; gain information that could aid in improved pre-operative patient education for deep brain stimulation (DBS), address unrealistic expectations before surgery, and meet patient expectations post-operatively.

Methodology: This study was a retrospective, single academic center, two-part design that included a questionnaire and chart review of 29 patients. Those included were patients with Parkinson's disease who had DBS programming at the academic center, between the years 2007 and 2014.

Results: Discrepancy was observed between expectations discussed, with 71.4% (*SEM*-8.7%) indicating they had been asked to verbalize expectations pre-operatively, compared to only 48.3% (*SEM*-9.4) of charts reviewed having documentation of pre-operative patient expectation discussions. One hundred percent of the sample were in at least some agreement that DBS met overall post-operative expectations, but only 46.4% (*SEM*-9.6%) were in complete agreement.

Conclusions: Overall, DBS patients' expectations were met to some degree; however, pre-op education should focus on what DBS does and does not improve, patients' expectations should be verbalized both pre and post-operatively, and documentation of expectations and education should be included in the patient chart.

Introduction

Parkinson's disease (PD) is a neurodegenerative disorder causing a lack of dopamine in the substantia nigra (Olanow & Pruisner, 2009). It affects approximately one million people in America and six million worldwide (parkinsonfoundation.org). This dopamine loss results in four cardinal motor signs: rest tremor, bradykinesia, rigidity, and loss of postural reflexes (Jankovic, 2008). When tremor, on/off fluctuations (optimal medication time versus time medication is not working), and dyskinesias become troublesome to manage, Deep Brain Stimulation (DBS) therapy may be considered as a treatment option (Okun & Foote, 2010).

Background of DBS for Parkinson's Disease

In 1997, this surgical option gained regulatory approval from the US Food and Drug Administration (FDA) for controlling essential tremor (ET) and PD tremor resistant to medication therapy. In 2002, the FDA granted conditional approval of DBS in subthalamic nucleus (STN) for patients with levodopa-responsive PD as add-on treatment (Coffey, 2009).

A good DBS surgical candidate is one with idiopathic PD who has motor improvement with levodopa, but continues to have troubling motor symptoms. In addition, the candidate should comprehend the surgical risks and be free of considerable cognitive impairment. Finally, a good candidate has practical expectations for what DBS can offer. If these criteria are met, DBS can offer PD patients with inadequate pharmacotherapy symptom reduction, improved functionality, and the possibility of decreased medications (Piper, Abrams, & Marks, 2005).

Based upon the above criteria for implanting DBS, the purpose of this study was three-fold. The first purpose was to determine if patients were asked to verbalize expectations of DBS pre-operatively, measured by self-report, as well as chart documentation. The second purpose

was to determine if patients' expectations were met post-operatively. The final purpose was to gain information that could aid in improved pre-operative patient education for DBS, address unrealistic expectations before surgery, and meet patient expectations post-operatively.

There is a paucity of literature related to DBS education and post-op patient expectations. However, the importance of repetition in learning and understanding of the contents pre-operatively for improved patient satisfaction post-operatively has been documented in the orthopedic literature, specifically in total knee replacements. Therefore, the broad application of the importance of repetitive learning and understanding, as noted in the orthopedic field, was utilized for this project.

Background of Pre-operative Education versus Met Post-operative Expectations

Scott, Howie, MacDonald, & Biant (2010) describe up to a 20% patient dissatisfaction rate with outcomes 12 months after total knee replacement (TKR). It is important to explain whether the lack of satisfaction is a result of patient selection, surgical technique, implant design, or the counseling and management of patient expectations. In these works, patient expectations were greatly associated with satisfaction. Managing psychological health and patient expectations may improve satisfaction.

Scott et al. (2012) described the importance of understanding patients' pre-operative expectations, and noted that knowing these expectations can enable surgeons to effectively educate and attain the best patient reported outcome measures (PROMs). Patients with total hip replacements (THR) have only 7% dissatisfaction scores while those with total knee replacements (TKR) have up to 20% dissatisfaction. In an attempt to better understand this dichotomy, patients undergoing both THR and TKR were sent questionnaires pre-operatively

and asked various questions, including detailed questions about expectations. Twelve months post-operatively, the questionnaires were sent for the second time. Findings suggested that for pre-operative education to be most successful, it should emphasize those expectations that are not likely to be met with surgery.

Parkinson's Disease Literature Review

The following databases were researched regarding PD-related research: Cumulative Index of Nursing and Allied Health Literature (CINAHL), Medline, Academic Search Premier, Health Source- Consumer Edition, Health Source Nursing/Academic, PsychARTICLES and PsychINFO. The key words used in the search included the following in various combinations: deep brain stimulation, Parkinson's disease, satisfaction, expectations, patient expectations, and ethics. The search was broadened again to include quality of life, in hopes of capturing more information, particularly research, which studied patient expectations. Initially, only literature from 2005 to present was requested. Due to lack of information, filters were adjusted to include 2000 to present. Inclusion criteria were not restrictive in order to gather more available information. Research and review articles from nursing, medicine and neuropsychological disciplines were included. Essentially, nothing that mentioned patient expectations was excluded.

A total of 14 articles and one clinical practice guideline meeting the criteria were included for this review. Of the 14 articles, eight were quantitative research studies and one was qualitative in nature. The remaining articles were comprised of various literature reviews, where patient selection and or expectations were referenced. The clinical practice guideline is geared

toward neuroscience nurses who care for patients with DBS. Literature Matrix detailed in Appendix 1.

While no research studies have been specifically conducted to explore the importance of the team (neurosurgeon, movement disorder specialist, nurses, and neuropsychologists) knowing what the patient expects from having DBS, there is at least an acknowledgment that this is a worthy topic for discussion. When patient expectations are noted, it is in the context of pre-operative and short-term post-operative time frames. Whether or not patient expectations change over time has not been addressed. Of the literature reviewed, three themes emerged: patient selection, quality of life, and patient expectations.

Patient Selection

The importance of appropriate patient selection should be underscored; this has been echoed over and over again in the literature. Potential candidates should have advanced idiopathic PD, have good levodopa response, and have (relatively) intact cognition (Breit, Schulz, & Benabid, 2004; Lopiano, et al., 2001; Morro, et al., 2009; Okun, et al., 2007; Sanghera 2004; & Tamma, et al., 2003). In addition, some consider age an important factor when selecting a candidate. Ideally, the patient would be less than 70 years of age (Lopiano et al., 2001; Okun et al., 2007), Sanghera et al., 2004; & Tamma et al., 2003).

Okun, et al. (2007) reiterates the magnitude of good patient selection, stating that it is the most important step of the DBS process. Nevertheless, the provider selecting patients is met with the difficult task of deciding appropriateness in an environment where no standardized regulations exist. In order to achieve clinical success post-operatively, it is imperative to choose candidates wisely (Lopiano et al., 2001; Tamma et al., 2003). Breit et al. (2004) correlated good

patient selection and use of the most favorable electrode implantation to the success of the surgery.

Post-operative realization of patient expectations is too late, particularly if the goal was unachievable. Family members may also have unrealistic expectations that should be addressed whenever possible. Unrealistic expectations may be a result of not fully understanding what surgery does and does not offer. This may manifest as a result of the secret desires for more, even when realistic expectations are explained. Some patients or families may have unrealistic goals sparked as a result of media depictions of other DBS patients or seeing the remarkable results of other patients (Sanghera, 2004; Uitti, 2000; Ward, et al., 2009).

Clinical practice guidelines state that patient education should begin early in the pre-operative evaluation process. What can realistically be expected from surgery should be described (Ward, et al., 2009). Thorough pre-operative education should be mandatory. Patient expectations should be reviewed when patient selection is in progress. The expectation should be written by the patient and included in the chart so this can be reviewed post-operatively for more meaningful assessment of goals attainment (Marks, 2011).

Quality of Life

Multiple studies addressed both motor and non-motor quality of life issues (Floden, et al., 2014; Ferrara et al., 2010; Montel, et al., 2009; Tuchman, 2004). While motor aspects of PD have improved with DBS, questions remain about how they affect quality of life and mental health. Montel, et al. (2009) conducted a study comparing patients who had DBS therapy and patients who were not stimulated, but were maintained on dopatherapy. This study revealed that depression and anxiety were not significantly impacted by the type of therapy received. Those

with DBS therapy scored higher in coping techniques, with no particular strategy showing significant differences. When studying the DBS group, quality of life decreased, in regards to speech only. While these results seem vague, suggestion was made that reviewing patient expectations and coping strategies would help prepare potential DBS patients for surgery.

Depression, considered a non-motor symptom of PD, impacts quality of life, regardless of the life situation. In PD patients with and without DBS, varying degrees of quality of life and depression exist. However, in a 2004 study by Tuchman, involving 108 patients, the overall satisfaction with the DBS experience was high, despite how depression and quality of life ranked. Those who had DBS over a longer period of time described less satisfaction with control of side effects than those with more recent implants, suggesting that quality of life for those with DBS should be followed closely. Longitudinal studies of those with DBS are needed to further understand the experience.

Ferrara et al, (2010) looked at health-related quality of life (HRQoL) and health satisfaction (HS). HRQoL is defined by World Health Organization (WHO) as an individual's perception of his/her position in life as it relates to culture, values, and personal goals. HS refers to an individual's interpretation of his/her physical, mental, and social status and function. HS and HRQoL values are measured by questionnaires. HS may highlight an issue of personal importance that may affect quality of life more than a perceived severe problem. The findings revealed improvements in various HRQoL issues, especially motor function and independence, after DBS. Life satisfaction following DBS did not improve perceived function at work, personal relationships, leisure activities, or living conditions. Likewise, there was no significant worsening in this area following DBS. Social, emotional, and cognitive factors tended to be better predictors of quality of life. Following DBS, energy level and life enjoyment improved

significantly. Particularly pertinent to this study, the researchers suggested studying HRQoL and HS in subsequent studies, focusing on enhancement of the patient selection process and consideration of specific clinical variables.

Folden, Cooper, Griffith, and Machado (2014) retrospectively studied the predictability of quality of life (QoL) measures in 85 patients after subthalamic DBS. They concluded that QoL improved on 39-item Parkinson's disease questionnaire (PDQ-39) in motor function, mood, and self-consciousness but not in speech, cognitive function and hallucinations. Patients who reported reduced QoL before surgery also reported comparatively QoL after surgery. They conclude that DBS increases or preserves QoL in the majority of patients. They acknowledged the emphasis on earlier DBS research has been on predictability of improved motor function after DBS, from the provider's perspective. With the current interest in QoL measures, the authors described a move towards understanding variables that account for DBS success, from the perspective of the patient.

Patient Expectations

In the 2014 literature review, Haswgawa, Samuel, Douiri, and AshkQoan (2014) studied the correlation between expectations, satisfaction, and outcomes in subthalamic (STN) DBS for PD. They used a modified 39-item Parkinson's disease questionnaire (PDQ-39) and a satisfaction questionnaire they developed and administered to 22 patients one day before surgery and again six months post-operatively. While most patients felt surgery fulfilled their expectations and were satisfied, a gap in expected change and actual change in PDQ-39 existed. They concluded expectations pre and post-operatively may play an important role in patient satisfaction and overall success of STN DBS.

Tornqvist, Ahlstrom, Widner, & Rehnstrom (2007) conducted a research study examining patient centered goals for tremor control. A comparison of patients own stated goals were obtained pre-operatively, and at 1, 6, and 12 months post-operatively (N=16). While it was specific to tremor control, it highlighted the importance of the patient's perspective. Further, it described how goals are generally outlined by various team members and not by the patient; the two are not necessarily interchangeable. It was suggested that when the provider and patient participate in goal setting and treatment planning, improved outcomes can be expected. The authors offered that specific research in this domain would be difficult to generalize, due to the individualized goals of each patient.

The expectations of each patient considering DBS as a treatment option should be discussed with the provider, prior to the operating room, in an effort to match surgical expectations with those of the patients. In addition, this offers the provider the opportunity to demystify expectations that are unrealistic (Breit, et al., 2004; Schermer, 2011). Benabid helped develop DBS in 1987. As a recognized expert in the field of DBS, Benabid, along with Breit and Schulz, further described unmet patient expectations as adverse DBS effects, negatively affecting the stimulation therapy.

A vast amount of research has been conducted looking at various benefits of DBS for the treatment of advanced PD, including improvement in motor aspects of the disease and quality of life. The benefits can be measured objectively by the provider using the Unified Parkinson's Disease Rating Scale (UPDRS), a tool used to measure disease progression. This tool combines subjective responses regarding mentation, behavior, mood, and activities of daily living and objective exam findings as described by the provider regarding motor aspects (Goetz et al., 2007).

Of these 14 articles, the importance of knowing the patient's expectations pre-operatively is acknowledged. When each expectation is explored, patient desires can be addressed, and unrealistic expectations discussed. Acknowledgement is also made that unmet patient expectations exist post-operatively. Long term studies have not been conducted to evaluate if patient expectations of DBS change over time. Outcome satisfaction by the provider and neurosurgeon does not equate to patient satisfaction and met expectations.

Theoretical Framework

This project is guided by Joyce Travelbee's Human-to-Human Relationship Model. The major concepts are as follow:

Human-to –human relationship- relations between nurse and patient that begin with the initial encounter and develop over time.

Original encounter- encompasses the first impressions by the nurse of the ill person and vice versa. At this point, each person is in a "stereotyped" role.

Emerging identities- nurse and patient move beyond the stereotyped role and see each other as individuals. At this point, a relationship is beginning.

Empathy- phase where one can share in the other's experience. Further promoting this process is similar experiences and the wish to understand another individual.

Sympathy- beyond empathy occurs as a result of nurse wanting to lessen the patient's illness or suffering.

Rapport- actions of the nurse that causes reduction of the patient's distress. The ill person and nurse are now interacting as human- to- human, rather than stereotyped roles. The ill person has

trust and confidence in the nurse's knowledge and skills because of her / his ability to recognize, respond to and value the individuality of the ill person (Tomey & Alligood ,2002, pp.22-25, 418-429) .

If the providers and programmers view patients as part of the team and the team and the entire team incorporates human to human contact, letting this contact develop into a trusted relationship, it is hypothesized that the team will more likely work collaboratively in setting and achieving realistic expectations.

Methods and Procedures

A retrospective, single academic center study was conducted in an attempt to evaluate patients' post-operative expectations of DBS. The study's two interventions included the use of a questionnaire (Table 6), as well as a retrospective chart review (chart review criteria can be found in Table 5). Recruitment selection was determined by using billing codes for Parkinson's disease and DBS with programming at any point from 2007-2014 in this Southeast university program, regardless of where the device was implanted, or where the device is currently programmed. Fifty two patients were contacted for voluntary participation. Patients who had devices removed for any reason were included, regardless if they had been re-implanted or not. Those who were knowingly deceased were excluded.

The initial attempt for recruitment was through mailed questionnaires. A 27 item questionnaire, mainly using a six point Likert scale, was used. The estimated time to complete this survey was 10-15 minutes. The questions were designed to evaluate met and unmet expectations, regardless of the realistic or unrealistic nature. Four questions were asked for broader information/patient opinion that could not otherwise be evaluated with use of Likert

scale. This questionnaire was created as no existing tool to measure expectations of DBS is available. As noted previously, the questions were developed using the Human-to-Human Relationship Model as a guiding theoretical framework. Content and face-validity of the questions were assessed by four University faculty with content and/or statistical expertise.

Those patients who did not mail questionnaires back within two weeks were contacted by phone. The time line for attempting phone interviews was two weeks. The phone recruitment was completed by the co-investigator. Of the phone calls made, no one opted to answer the questions over the phone, but some verbalized they were still working on questionnaires and would mail. After four weeks, a total of 32 questionnaires were received. One was returned as undeliverable and one patient returned stating unable to participate as hospitalized. Additionally, one family member contacted the research coordinator to report patient's recent death.

Chart reviews of those who had returned questionnaires were then completed. The main purpose of this review was to determine if patients' expectations were documented pre-operatively and post-operatively. Additional information gathered in the chart review included gender, date of birth, education level, ethnicity, age at symptom onset, age PD diagnosed, age at implant(s), most troublesome symptom(s) prompting DBS, and implanted target area of the brain. As a result of the chart review, one patient's questionnaire was excluded as it was determined that the diagnosis at time of implant was for essential tremor, not Parkinson's disease.

This was a one-time survey and participation concluded at the end of the questionnaire, or when the patient desired to stop answering questions. If completed by mail, it was returned in an addressed, pre-paid envelope and mailed to the research coordinator. The questionnaires were

given to the PI. Chart reviews were completed on the returned questionnaires. At the end of four weeks, data was de-identified, entered into Excel, and sent electronically to Paul Loprinzi PhD for data analysis. The analytical approach computed the univariate analyses describing the mean/prevalence of outcomes for each patient. STATA, version 12 was used. The results were relayed to the principle investigator.

Barriers

Several potential barriers to this project were identified. This is a retrospective study with a small sample size. The PI was not blinded. There are no known tools that have been assessed for validity and reliability. Different practitioners provided the pre-operative education to the patients and what was specifically included in the education is not known. Documentation, or the lack of documentation, may be different than what was actually done. Patients participating in the project may have micrographia and/or tremor, possibly leading to problems with legibility. Illiteracy is a potential barrier. Potential barriers to a successful phone interview were identified as dysarthria, hypophonia, and marked hearing loss.

Risks

Patients could answer as many or as few questions desired and could decline the survey at any point. Permission was without coercion or repercussion. According to the Human Participant Studies-Risk Assessment Guide, updated in 2014, there may be emotional stress related to answering questionnaires about personal experiences.

Results

Among the 52 questionnaires that were mailed, 32 were returned and 29 were included in the analysis, for a return rate of 55.8%. One questionnaire was returned as undeliverable. One was returned unanswered due to hospitalization. One was omitted as chart review revealed a diagnosis of essential tremor, rather than PD. Among the 29 participants, 75% were implanted at this academic center, 71% male, 100% Caucasian, 43% had high school diploma/ GED, 43% had Associates degree or higher; the mean age at implant was 66.7 years. Of the 29 participants, 23 were implanted in the subthalamic nucleus, four were implanted in the globus pallidus (GPi), and two were targeted in the ventral intermediate nucleus (VIM) of the thalamus.

With regard to the provision of education for DBS, when participants were asked to identify all sources of education received, 96.4% received this information from the provider that managed PD, 60.7% from the neurosurgeon, 46.4% from Medtronic, 14.3% from nurse/staff, 46.4% from internet, and 14.3% from other (i.e. support group, seminars).

Regarding troublesome symptoms prompting desire for DBS, the top three symptoms listed were tremor 79.3%, dyskinesias 24.1%, and rigidity 13.8%. Another 6.9% described inadequate on time and medications as troublesome. There were various other symptoms such as walking and reduced quality of life with 10.3% each. Balance, freezing of gait (FOG), and writing each accounted for 3.4% description as troublesome. See Figure 1.

A discrepancy was noted between self-reported verbalization of expectations versus chart review. For example, when asked, 71.4% of the participants (*SEM*- 8.7%) indicated that they had been asked their expectations pre-operatively, compared to 48.3% (*SEM*- 9.4%) identified by documentation in the chart review.

With regard to patient expectations met post-operatively, 100% of the sample were in at least some agreement that post-op expectations were met. More specifically, 46.4 % (*SEM*- 9.6%) strongly agreed, 39.3% agreed (*SEM*- 9.4%), and 14.3% (*SEM*- 6.7%) somewhat agreed.

The level to which DBS met realistic expectations is shown in Table 1. Expectations were defined as met if the participants entered strongly agree, agree, or somewhat agree. With regard to tremor and rigidity, 82 % of sample had the expectation met. Seventy five percent of the sample agreed that DBS met expectation for bradykinesia. Eighty-five percent had met their expectation for improvement of on time. Eighty-two percent had expectation met for dyskinesias. Sixty eight percent were in agreement that DBS met expectation for dystonia.

Table 2 depicts pre-op expectations documented in charts versus what the participants described on their questionnaire as desired expectation for wanting DBS, followed by their answer if expectation was met, somewhat met, or not met. Regardless if comparing the documented pre-op expectation column or the desired expectation column, there is a large portion of realistic expectations identified (highlighted in green), as well as a large portion of met expectations. For example, of the 14 charts with pre-op documentation, 34.5% wanted tremor improvement, whereas 75% of the 29 participants who completed the questionnaire, identified tremor as an expected outcome for having DBS. Of the 28 participants who answered this question, 79.3% reported they had met the expectation for tremor improvement.

Medicine reduction was documented as an expected outcome in 31% of the 14 chart reviews, while 21.4% of the 29 participants identified this as a desired expectation of DBS on the questionnaire. This expectation was met in 13.8%, whereas, 3.4% had somewhat met the

expectation, and 3.4% did not have expectation met. This is highlighted in yellow and is not necessarily an unrealistic expectation, but is also not guaranteed.

Expectations highlighted in red would not necessarily be considered realistic expectations. For example, of the 14 charts with pre-op expectations documented, 10.3% identified improvement in sleep as an expectation of DBS. Of the 29 participants, one participant identified this on the questionnaire as a desired expectation for having DBS and stated this expectation was met. There are many things to consider with sleep. For example, if sleep is problematic due to a cumbersome dosing schedule and alarms must be set to stay on schedule, or if improving tremor helps sleep be achieved, this may be realistic. However, there are multiple reasons that would need to be considered, such as insomnia, sleep apnea, nocturia, etc., with which improvement would not be expected.

With regard to the question that DBS helped overall, 100% were in agreement. Agreement included all answers that implied any degree of agreement: strongly agree, agree, or somewhat agree. Of the 29 participants, 64.3% (SEM- 9.2%) were in strong agreement, 28.6% (SEM- 8.7%) were in agreement and 7.1% (SEM- 5%) somewhat agreement. One hundred % of the participants would have DBS all over again, with 75% (SEM- 8.3%) in strong agreement, 21.4% (SEM- 7.9%) in agreement, and 3.6% (SEM- 3.6%) in somewhat agreement. One hundred percent would recommend DBS to someone else with PD, with 64.3% (SEM- 9.2%) in strong agreement, 28.6% (SEM- 8.7%) in agreement, and 7.1% (SEM- 5%) in somewhat agreement. With regard to pre-op education preparing for what the device does and does not improve, 96% were in agreement. Of this 96%, the level of strong agreement shifted downward: 32.1% (SEM- 8.9%) strongly agreed, 46.4% (SEM- 9.6%) agreed, and 17.9% (SEM- 7.4%) somewhat agreed. Of particular interest, 3.6% (SEM- 3.6%) strongly disagreed. See Figure 2.

Conclusions

Gaps exist between documentation of patients verbalized expectations pre-operatively and post-operatively. Despite met DBS expectations, a gap also exists between realistic and unrealistic expectations. Education should focus on what is and is not realistic and this should begin pre-operatively. Verbalization during neuropsychological evaluation, with a separate follow up clinic appointment to individually address each expectation, may aid in patients feeling more prepared for what DBS can and cannot provide. Whether or not patient expectations change over time has not been addressed. Additional research in this area is needed to assure that post-operative expectations are not overlooked, and can realistically be attained.

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Appendices

Figure 1

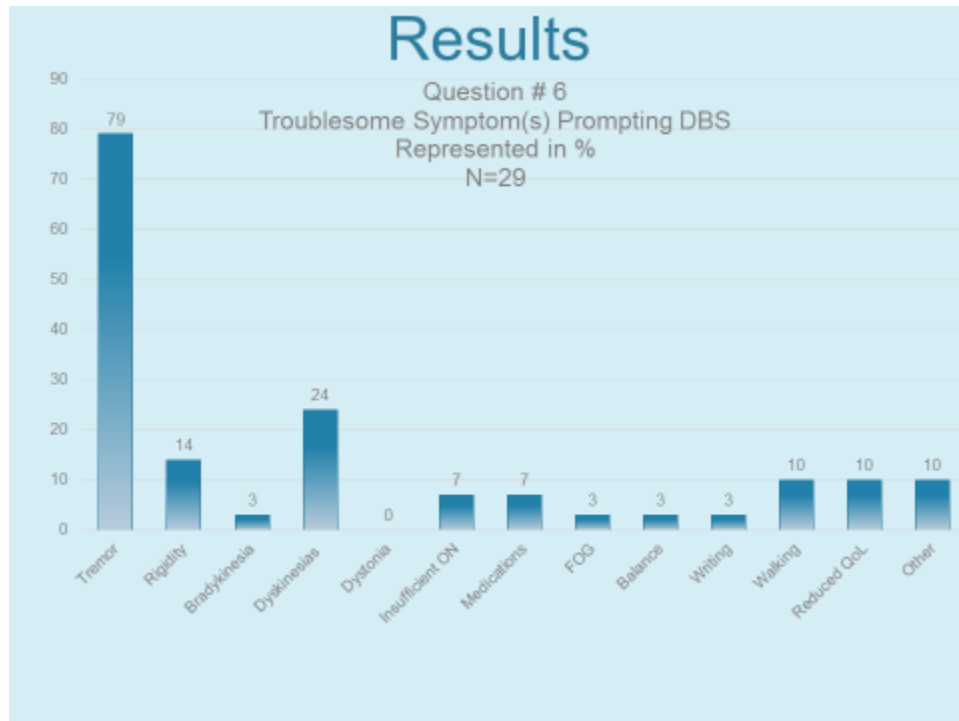


Table 1

Results : question # 14,15,16,17,18 &19
Realistic Patient Expectation Table

	DBS met my Expectation for Improving...		Strongly Agree	Agree	Somewhat Agree	Neither Agree or Disagree	Somewhat Disagree	Disagree	Strongly Disagree	Didn't have DBS for this
		%	%	%	%	%	%	%	%	%
Question 14	Tremor N=29 82	61	14	7						18
Question 15	Rigidity N=29 82	32	29	21	4	4				10
Question 16	Slowness N=29 75	29	21	25	7	4	7			7
Question 17	On time N=28 85	39	25	21	11					4
Question 18	Dyskinesia N=29 82	36	25	21	7					10
Question 19	Dystonia N=29 68	21	29	18	7					25

The third, fourth and fifth columns, which are circled, indicate some level of agreement.

The red numbers in the second column indicate the total percent that had some level of agreement for each of the listed symptoms.

Table 2

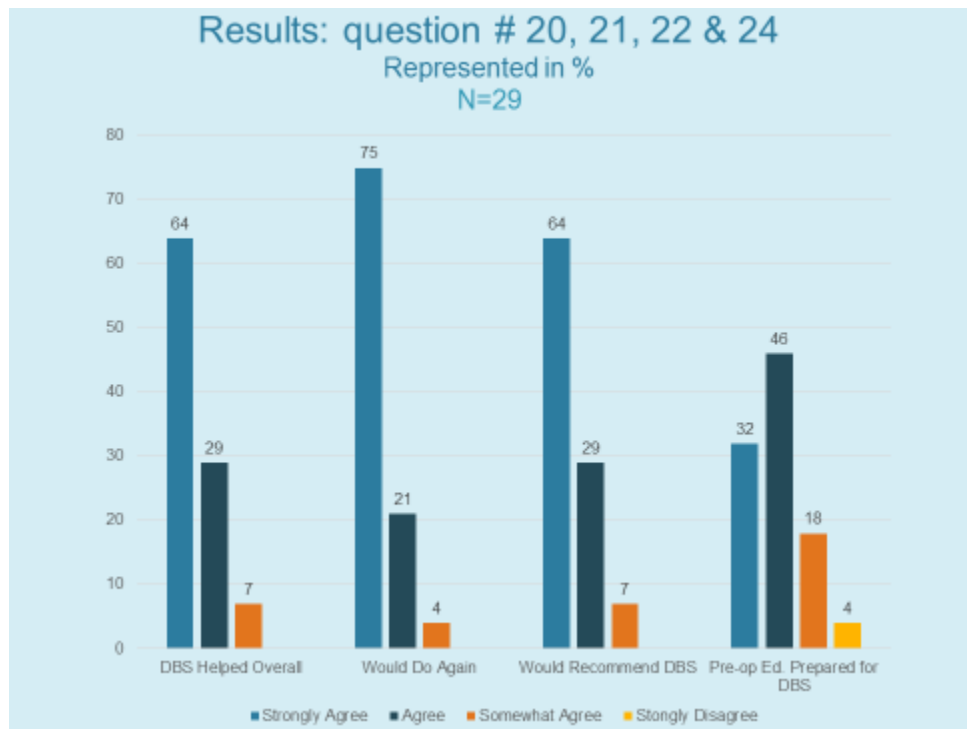
Results : question # 25 & 26					
Documented Pre-op Expectations vs Retrospective Patient Expectations Met and Unmet					
Improve...	Pre-op Expectation Documented N=14 %	Desired Expectation for having DBS N=29 %	Expectation Met N=28 %	Expectation Somewhat Met N=28 %	Expectation Not Met N=28 %
tremor	35	75	79	3	
rigidity	10	8	10		3
bradykinesia		7	3	3	
on time	21	21	17	3	
dyskinesias	17	18	21	3	
dystonia	3	7	3	3	
reduce meds	31	21	14	3	3
sleep	10	4	3		
freezing of gait (foog)	7	4			
speech		4			3
balance	3	4			3
walking	7	14			10
writing		11	14		
QoL		21	17		3
(reduce) pain		7		3	3
eat w/ utensils		4	7		
use tools				3	
(help) PD		11	7	3	
ride bike		4	3		
use of arm		4	3		
normal life		4	3		
other	24	4	3		

The rows that are highlighted in green represent symptoms that are expected to improve following DBS.

The row highlighted in yellow represents the possibility of PD medication reduction following DBS.

The rows highlighted in red represent symptoms that are unlikely to improve following DBS, unless the cause of the symptom is directly related to PD symptoms that may have been alleviated by DBS.

Figure 2



Appendix 1

Literature Matrix

Major Themes Author/Year	Aim/Purpose	Methodology/Sample size
Patient Selection		
Tamma, L., et al. (2003)	Describe pre/post-op UPDRS -Speaks to patient selection	Quantitative, pre/post op comparison N=30
Moro, E., et al. (2009)	Develop a screening tool for DBS candidates	Quantitative, RAND/UCLA method N=1728 hypothetical cases
Breit, S., et al. (2004)	Hypothesize mechanism of high-frequency stimulation	Review
Okun, M.S., et al. (2007)	Review key aspects of DBS and issues neuropsychologist will address	Review
Lopiano, L., et al., (2001)	Present protocol of patient selection	Quantitative, retrospective; N=20
Sanghera, M.K. (2004)	Review pre-op and immediate post-op aspects of DBS and report team experiences	Review
Patient Expectations		
Hasegawa, H. et al., (2014)	Evaluate PD patient expectations pre/post op with PDQ-39 and satisfaction survey	Quantitative, pre/post op comparison of questionnaires
Schermer, M. (2011)	Review of relevant medical and ethical literature as it relates to DBS	Mini
Uitti, R.J. (2000)	Review of surgery for PD with emphasis on relevant info for PCP	Review (CME)
Tornqvist, A. L., et al. (2007)	Evaluate results of VIM DBS from the patients perspective	Quantitative, pre/post op comparison of questionnaires; N= 16
Ward, C. et al., (2009)	Review and evaluate literature to create reference for neuroscience nurses who deliver care to those with DBS	Clinical Practice Guidelines
Susatia, F. et al., (2011)	Troubleshoot problems with DBS that may be accountable for less than expected outcomes	Text on DBS management
Quality of Life (QoL)		
Montel, S.R. & Bungener, C. (2009)	Investigate coping measures of PD pts wit DBS in regards to QoL	Qualitative Comparison of PD pts with DBS & those with dopathery only; with DBS N=40, without DBS N=40
Ferrara, J. et al., (2010)	Provide pilot data about outcomes following DBS using a new, recently validated, DBS health related QoL tool to measure life satisfaction	Quantitative, prospective clinical assessments N=23
Floden, D. et al., (2014)	Examine disease, treatment, cognitive, and psychological factors associated with QoL pre/post op and assess predictability of QoL	Quantitative, retrospective; N=85
Tuchman, M. (2004)	Examine QoL and depression of PD with DBS	Quantitative, descriptive & explanatory N=108

Appendix 2

Chart Review Checklist

NAME _____ DOB _____ - _____ - _____

MALE / FEMALE

EDUCATION LEVEL _____

HOW LONG HAD PD BEFORE IMPLANTED?

SYMPTOM ONSET _____ CONFIRMED PD _____

MOST TROUBLESOME SYMPTOM(S) PROMPTING DBS? _____

AGE(S) AT IMPLANTATION- 1ST SIDE- _____ 2nd SIDE _____

YEAR IMPLANED 1ST SIDE (IF KNOWN) _____ / 2nd SIDE _____

TARGET? STN GPi VIM

WHERE

IMPLANTED? _____ SURGEON? _____

WERE EXPECTATIONS DOCUMENTED BEFORE SURGERY? YES NO UNKNOWN

WHERE CAN THIS DOCUMENTATION BE FOUND?

NP EVAL- (date) _____ MDC VISIT _____

SURGEON PRE-OP NOTE? _____ OTHER _____

WHAT WERE EXPECTATIONS IF KNOWN? _____

IS THERE DOCUMENTATION OF MET OR UNMET EXPECTATIONS POST-OP?

SHORT TERM

3Mos _____ 6Mos _____ 12Mos _____

LONG TERM

3Yr _____ 5Yr _____ Beyond _____

9. What is the highest grade you completed in school? **Please circle best answer.**

- | | |
|---|--|
| -Did not attend school | -Trade/ technical/ vocational training |
| -1 st to 5 th grade | -Associate degree |
| -6 th to 8 th grade | -Bachelor's degree |
| -Some high school, no diploma | -Master's degree |
| -High school graduate or equivalent | -Doctorate degree |
| -Some college, no degree | |

10. Who provided your education about DBS surgery? **Check all that apply.**

- _____ Provider that treated your Parkinson's disease (physician,
nurse practitioner, physician assistant)
- _____ Neurosurgeon
- _____ Medtronic Educational Tools (i.e. Videos, DVDs, brochures)
- _____ Nurse or other staff member
- _____ Internet
- _____ Other (i.e. support group, seminars, TV)
- _____ No one educated me about DBS surgery

11. Using the following scale, please rate how helpful each of the following sources were in providing your education before surgery? If no one educated you, please skip this question.

- 1- Most helpful
- 2- Very helpful
- 3- Helpful
- 4- Somewhat helpful
- 5- Not helpful
- 6- Did not receive education from this source

_____ Provider that treated your Parkinson's disease (physician, nurse practitioner, physician assistant)

_____ Neurosurgeon

_____ Medtronic Educational Tools (i.e. Videos, DVDs, brochures)

_____ Nurse or other staff member

_____ Internet

_____ Other (i.e. support group, seminars, TV)

Please circle the following answers.

12. Before you had DBS surgery, did anyone ask you what your expectations were?

-Yes

-No

13. Did you have DBS surgery with the University of Louisville Movement Disorder program?

-Yes

-No

On the following questions, please circle the ONE answer that best describes your level of agreement.

14. DBS met my expectation for improvement of tremor?

- [1] Strongly agree
- [2] Agree
- [3] Somewhat agree
- [4] Neither agree or disagree
- [5] Somewhat disagree
- [6] Disagree
- [7] Strongly disagree
- [8] N/A- I did not have DBS for tremor.

15. DBS met my expectation for improvement of stiffness/rigidity.

- [1] Strongly agree
- [2] Agree
- [3] Somewhat agree
- [4] Neither agree or disagree
- [5] Somewhat disagree
- [6] Disagree
- [7] Strongly disagree
- [8] N/A- I did not have DBS for stiffness/rigidity.

On the following questions, please circle the ONE answer that best describes your level of agreement.

16. DBS met my expectation for improvement in slowness of movement.

[1] Strongly agree

[2] Agree

[3] Somewhat agree

[4] Neither agree or disagree

[5] Somewhat disagree

[6] Disagree

[7] Strongly disagree

[8] N/A- I did not have DBS for slowness of movement.

17. DBS met my expectation for improving on/off time (the time when you feel your symptoms are best controlled)?

[1] Strongly agree

[2] Agree

[3] Somewhat agree

[4] Neither agree or disagree

[5] Somewhat disagree

[6] Disagree

[7] Strongly disagree

[8] N/A- I did not have DBS for improvement of on/off time.

On the following questions, please circle the ONE answer that best describes your level of agreement.

18. DBS met my expectation for improving dyskinesias (dancing, wiggling, or writhing movements)?

[1] Strongly agree

[2] Agree

[3] Somewhat agree

[4] Neither agree or disagree

[5] Somewhat disagree

[6] Disagree

[7] Strongly disagree

[8] N/A- I did not have DBS for dyskinesias.

19. DBS met my expectation of improving dystonia (muscle pulling, cramping)?

[1] Strongly agree

[2] Agree

[3] Somewhat agree

[4] Neither agree or disagree

[5] Somewhat disagree

[6] Disagree

[7] Strongly disagree

[8] N/A- I did not have DBS for dystonia.

On the following questions, please circle the ONE answer that best describes your level of agreement.

20. DBS has helped me overall.

- [1] Strongly agree
- [2] Agree
- [3] Somewhat agree
- [4] Neither agree or disagree
- [5] Somewhat disagree
- [6] Disagree
- [7] Strongly disagree

21. If I had it to do all over again, I would still have DBS.

- [1] Strongly agree
- [2] Agree
- [3] Somewhat agree
- [4] Neither agree or disagree
- [5] Somewhat disagree
- [6] Disagree
- [7] Strongly disagree

On the following questions, please circle the ONE answer that best describes your level of agreement.

22. I would recommend DBS to others living with Parkinson's disease.

- [1] Strongly agree
- [2] Agree
- [3] Somewhat agree
- [4] Neither agree or disagree
- [5] Somewhat disagree
- [6] Disagree
- [7] Strongly disagree

23. DBS met my overall expectations.

- [1] Strongly agree
- [2] Agree
- [3] Somewhat agree
- [4] Neither agree or disagree
- [5] Somewhat disagree
- [6] Disagree
- [7] Strongly disagree

On the following questions, please circle the ONE answer that best describes your level of agreement.

24. The education I received before surgery prepared me for what this device does and does not improve.

[1] Strongly agree

[2] Agree

[3] Somewhat agree

[4] Neither agree or disagree

[5] Somewhat disagree

[6] Disagree

[7] Strongly disagree

[8] N/A- I did not have DBS for this symptom.

Please answer in your own words.

25. What did you expect DBS to do for you? **Please list.**

26. Which of these expectations were met by DBS? _____

UofL Institutional Review Boards
IRB NUMBER: 15.0018
IRB APPROVAL DATE: 01/22/2015

Gap in Patient Expectations of Deep Brain Stimulation for the Treatment of Parkinson's Disease

2-3-15

Dear ,

You are being invited to participate in a research study by answering the attached survey about patient expectations of Deep Brain Stimulations (DBS) for the treatment of Parkinson's disease. There are no known risks for your participation in this research study, although emotional stress can occur when answering questions about personal experiences. The information collected may not benefit you directly. The information learned in this study may be helpful to others. The information you provide will aid in understanding how to improve pre-operative education for DBS so that patient expectations are met post-operatively. Your completed survey will be stored in a locked cabinet in a locked office in the Movement Disorder Clinic. The survey will take approximately 15 minutes to complete.

Individuals from the Department of Neurology, the Institutional Review Board (IRB), the Human Subjects Protection Program Office (HSPPPO), and other regulatory agencies may inspect these records. In all other respects, however, the data will be held in confidence to the extent permitted by law. Should the data be published, your identity will not be disclosed.

Taking part in this study is voluntary. By completing this survey you agree to take part in this research study. You do not have to answer any questions that make you uncomfortable. You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. If you decide not to be in this study or if you stop taking part at any time, you will not lose any benefits for which you may qualify.

If you have any questions, concerns, or complaints about the research study, please contact: Annette Robinson, 502-540-3585.

If you have any questions about your rights as a research subject, you may call the Human Subjects Protection Program Office at (502) 852-5188. You can discuss any questions about your rights as a research subject, in private, with a member of the Institutional Review Board (IRB). You may also call this number if you have other questions about the research, and you cannot reach the study doctor, or want to talk to someone else. The IRB is an independent committee made up of people from the University community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has reviewed this research study.

If you have concerns or complaints about the research or research staff and you do not wish to give your name, you may call 1-877-852-1167. This is a 24 hour hot line answered by people who do not work at the University of Louisville.

Sincerely,

Kathrin LaFaver, MD

Colleen D. Knoop, APRN

Key Personnel

Key personnel for this project included the principle investigator, Colleen D, Knoop, DNP-C and the doctoral committee, and statistician. The chairperson for this project was Kathy Hager, DNP, APRN, FNP-C, CDE. Michael Park, MD, PhD served as the expert clinic advisor. Paul Loprinzi, PhD, and Lynette Galloway, DNP, APRN, PNP-BC, FNP-BC were both faculty advisors. Paul Loprinzi PhD was also the statistician for this project. To replicate this study, contact should be made to the principle investigator cdknoop@outlook.com

Stakeholders

The stakeholders for this project are identified as the primary investigator, providers that manage those with PD and DBS patients' pre and post-operatively, the patients and their families, the organization, health care personnel, insurance companies, manufacturers of DBS devices and Parkinson's' Interest Groups. This study represents data gathered from an academic center in southeastern USA.

Resources

Resources needed for this project are the principle investigator, doctoral committee, patient participation, contact person (for phone interviews), and statistician.



Approvals

This project was approved by the principle investigator's doctoral committee. Once this was received, IRB approval from the university where the patients were programmed was obtained. IRB approval from Bellarmine University was also obtained since this is a doctoral project for this university.