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Psychiatric and Social Outcome After Deep Brain Stimulation for Advanced Parkinson's Disease

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Abstract

Background: The aim of this study was to assess psychiatric and social outcome 12 months after bilateral deep brain stimulation (DBS) of the globus pallidus pars interna (GPi) and subthalamic nucleus (STN) for advanced Parkinson's disease (PD).

Methods: We randomly assigned patients to receive GPi DBS (n = 65) or STN DBS (n = 63). Standardized psychiatric and social questionnaires were assessed at baseline and after 12 months.

Results: No differences were found between GPi DBS and STN DBS on psychiatric evaluation. Within-group comparisons showed small but statistically significant changes on several measures in both groups. Descriptive statistics indicated slight changes in social functioning. Marital satisfaction of patients and partners remained relatively stable after GPi and STN DBS.

Conclusions: We found neither differences in psychiatric and social outcome between GPi DBS and STN DBS nor any relevant within-group differences. The decision for GPi DBS or STN DBS cannot be based on expected psychiatric or social effects. © 2015 International Parkinson and Movement Disorder Society

Key Words: randomized controlled trial; Parkinson's disease; deep brain stimulation; psychiatry

Deep brain stimulation (DBS) of the globus pallidus pars interna (GPi) or the subthalamic nucleus (STN) are treatment options in advanced Parkinson's disease (PD). Concerns have been raised regarding the psychiatric side effects of DBS, especially of STN DBS.[1-5] Additionally, STN DBS patients would experience difficulties in several aspects regarding social adaption after surgery.[1] Possible psychiatric side effects are important because they greatly impact quality of life in PD.[6-8]

For these reasons, scales assessing psychiatric symptoms and social functioning were added to the protocol of the Netherlands SubThalamic And Pallidal Stimulation (NSTAPS) trial, in which the effects of bilateral GPi DBS and STN DBS are compared.[9] Here we report the psychiatric outcome 12 months after DBS (between-group and within-group analyses). Furthermore, we report descriptive statistics on psychiatric diagnoses and social functioning before and after GPi DBS and STN DBS.

Methods

This article presents secondary outcomes on psychiatric and social measures from the NSTAPS trial. The study design and primary outcomes have been reported previously.[9] This trial was registered with www.controlled-trials.com, number ISRCTN85542074.

Patients and Procedures

We enrolled a total of 128 patients between January 2007 and March 2011. Information on inclusion and exclusion criteria as well as stereotactic surgery is described elsewhere.[9] Psychiatric and social questionnaires were assessed in the on-medication phase at baseline and at 12 months, with the stimulators turned on at 12 months. The medical ethics committee approved the study protocol. Patients provided written informed consent.

Outcome Measures

Extensive standardized psychiatric evaluation, performed at baseline and at 12 months, consisted of interviews and self-report questionnaires based on *Diagnostic and Statistical Manual of Mental Disorders*–classified psychiatric disorders, and quantitative self-reports on characteristics and severity of psychopathology, personality, mood and affect, and social functioning.[10]

Between-group and within-group analyses were performed for the following four psychiatric scales. The Young Mania Rating Scale (YMRS) was used to assess the severity of manic symptoms.[11] Mood was assessed

with the Hospital Anxiety and Depression Scale (HADS).[12] The Positive and Negative Affect Schedule (PANAS-X) was used to measure affect.[13] The Five Factor Personality Inventory-II (FFPI) was used to assess the "Big Five" factors of personality.[14]

Descriptive analyses were performed on data from the following questionnaires. We measured psychopathology with the Mini-International Neuropsychiatric Interview (MINI).[15] To obtain a quantitative measure of suicidal ideation, a short interview was used from the Netherlands Study on Depression and Anxiety (NESDA).[16] Social functioning was assessed using a social participation and a network questionnaire (NESDA).[16] The current work situation was evaluated,[17] as well as sexual functioning of patients.[18] Marital satisfaction was assessed by interview (NESDA). Both patients and their partners rated personal characteristics of their significant other (Supplemental Data I).

Statistical Analyses

Analyses were based on the intention-to-treat principle. We performed linear regression to compare GPi DBS and STN DBS on the psychiatric scales (the YMRS, HADS, PANAS, and FFPI). Within-group differences of GPi DBS and STN DBS before and 12 months after surgery were assessed using paired *t* tests or Wilcoxon signed rank tests.

We created imputation models to assess possible differences in outcome attributable to incomplete data on the YMRS, HADS, FFPI, and PANAS. The significance level was set at 0.05 (two-sided test). In view of the explorative nature of this study, we did not correct for multiple testing.[19] Statistical analyses were performed with SPSS software V.20.0.0.1.

With regard to the descriptive analyses on psychiatric diagnoses and social functioning before and after

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TABLE 1. Demographic and clinical characteristics at baseline

	GPi DBS (n = 65)	STN DBS (n = 63)
Age (mean ± SD), y	59.1 ± 7.8	60.9 ± 7.6
Age of onset PD (mean ± SD), y	48.5 ± 7.6	48.6 ± 9.4
Male sex, no. (%)	44 (68)	44 (70)
Duration of PD (mean ± SD), y	10.8 ± 4.2	12.0 ± 5.3
Duration of use of medication for PD (mean ± SD), y	9.0 ± 3.9	9.5 ± 5.6
Hours per day spent in on drug phase[a] (mean ± SD) – h	6.5 ± 3.6	6.3 ± 4.4
On drug phase Hoehn & Yahr stage (median [range])	2.5 [0-4]	2.5 [0-4]
Levodopa equivalent dose[b] ≥ 1000 mg/d, no. (%)	43 (69)	43 (68)
Mattis Dementia Rating Scale (mean ± SD; range, 0-144)	138.7 ± 4.0	138.1 ± 5.1

[a]Calculated using a 3-d diary.
[b]Levodopa equivalent dose = regular levodopa dose × 1 + slow-release levodopa × 0.75 + bromocriptine × 10 + apomorphine × 10 + ropinirole × 20 + - × 0.75 + bromocriptine × 10 + apomorphine × 10 + ropinirole × 20 + pergol- 0.75 + bromocriptine × 10 + apomorphine × 10 + ropinirole × 20 + pergolid- 0.75 + bromocriptine × 10 + apomorphine × 10 + ropinirole × 20 + pergolide- × 10 + apomorphine × 10 + ropinirole × 20 + pergolide × 100 + pramipexole- × 10 + ropinirole × 20 + pergolide × 100 + pramipexole × 100 + (regular levodopa dose + [slow-release levodopa × 0.75]) × 0.2 if taking entacapone.
GPi, globus pallidus pars interna; STN, subthalamic nucleus.

GPi DBS and STN DBS, we calculated frequencies of dysfunctions, without the use of formal statistical tests. For all statistical analyses, patients who completed the specific scales at both assessments were included.

Results

A total of 128 patients were randomly assigned to either GPi DBS (65 patients) or STN DBS (63 patients). Baseline characteristics are displayed in Table 1.[9] Three patients withdrew from the GPi group, and none from the STN group. Patterns of missing data of the YMRS, HADS, FFPI, and PANAS were analyzed. On average, 18.3% of the data points were missing. Missing data did not significantly differ between GPi DBS and STN DBS. The presented results are based on the non-imputed dataset (imputed data yielded similar outcomes and are available on request).

Between-Group Comparison (GPi DBS vs STN DBS)

The four psychiatric questionnaires, the YMRS, HADS, PANAS, and FFPI, indicated no significant differences between GPi DBS and STN DBS (Table 2).

Within-Group Comparison

GPi DBS

The YMRS scores were statistically significantly lower at 12 months (-1.1 from a baseline score of 3.2 out of 60, $P = 0.04$). No significant differences were found on the HADS. The PANAS positive affect score was significantly lower ($P = 0.01$) at 12 months, but the absolute difference was small (-2.7 from a baseline score of 32.8 out of 50). The 12-month FFPI showed

TABLE 2. Between-group and within-group analyses of the YMRS, HADS, PANAS, and FFPI

	Baseline		12 months		*p* between-group	*p* within-group	
	GPi	STN	GPi	STN	GPi vs. STN	GPi	STN
YMRS							
Total score*	2 (1-4)	1 (0-4)	1 (1-3)	2 (1-3)	0.77	0.04	0.42
HADS							
Total score	12.2 (4.4)	11.3 (6.3)	12.0 (6.5)	11.6 (6.3)	0.75	0.81	0.62
Anxiety	6.1 (2.7)	5.8 (3.4)	5.9 (2.9)	5.4 (3.3)	0.54	0.51	0.31
Depression	6.0 (2.8)	5.5 (3.4)	6.1 (4.5)	6.2 (3.8)	0.41	0.90	0.07
PANAS							
Positive affect	32.8 (5.7)	33.0 (6.5)	30.1 (6.0)	31.4 (6.3)	0.41	0.01	0.02
Negative affect	19.3 (6.0)	18.8 (5.9)	18.7 (5.9)	19.0 (6.7)	0.73	0.63	0.86
FFPI							
Extraversion	-0.2 (1.0)	-0.1 (1.1)	-0.5 (1.1)	-0.1 (1.1)	0.07	0.01	0.67
Agreeableness	2.8 (1.1)	2.8 (1.1)	2.6 (1.0)	2.5 (1.2)	0.89	0.02	0.13
Conscientiousness	0.8 (1.1)	0.7 (1.3)	0.7 (1.1)	0.7 (1.0)	0.74	0.48	0.99
Emotional stability	1.0 (0.9)	1.2 (1.0)	0.9 (0.9)	1.0 (1.0)	0.92	0.45	0.13
Autonomy	0.9 (1.1)	1.2 (0.8)	0.6 (0.80)	0.9 (0.8)	0.66	0.06	0.03

All values are mean (SD), except for those marked with an *; these are median (interquartile range). *P* between-group was calculated using linear regression to adjust for baseline scores. The 12-month score was entered as the dependent variable, and the baseline score and treatment group were entered as independent variables. Before linear regression, the YMRS scores were log transformed because of the skewness of the data. *P* within-group was calculated using paired *t* tests or Wilcoxon signed-rank tests, when appropriate.
YMRS, Young Mania Rating Scale, GPi n = 49, STN n = 53; HADS; Hospital Anxiety and Depression Scale, total score: GPi n = 53, STN n = 54; PANAS, Positive and Negative Affect Schedule, GPi n = 38, STN n = 40; FFPI, Five Factor Personality Inventory-II, GPi n = 51, STN n = 51. GPi, globus pallidus pars interna; STN, subthalamic nucleus.

significantly lower scores on extraversion ($P = 0.01$) and agreeableness ($P = 0.02$).

STN DBS

At 12 months, no significant differences were found on the YMRS and the HADS. The PANAS positive affect score was significantly lower ($P = 0.02$) at 12 months, but the absolute difference was small (-1.6 from a baseline score of 33.0 out of 50.0). The 12-month FFPI showed significantly lower scores on autonomy ($P = 0.03$; see Table 2).

Descriptive Comparison of Psychiatric and Social Functioning

Psychiatric evaluation using the MINI showed similar presence of dysthymia (both 0), (hypo-) manic episode (GPi 0, STN 1), panic disorder (GPi 1, STN 0), alcohol abuse and dependence (both 0), and psychotic disorder (GPi 5, STN 4), in the 12 months after surgery. Depressive disorders were reported more after STN DBS (GPi 7, STN 11), agoraphobia was reported more after GPi DBS (GPi 9, STN 4: supplement II). Suicidal ideation in the week before the psychiatric evaluation was present in none of the GPi DBS patients and one DBS STN patient at baseline, and in one GPi DBS patient and two STN DBS patients in the week before the 12-month evaluation.

Regarding societal participation, more than 80% of patients in both DBS groups were a member of an organization, which remained stable over time. Most patients who were a member also attended meetings of their organizations. Most patients were members of a PD patient organization or a sport or religious organization (Supplemental Data III). Regarding networking, the number of friends a patient thought they had remained stable (GPi DBS: four friends at baseline and at 12 months, STN DBS: five friends at both assessment). Most patients were unfit for work (GPi n = 23, STN n = 22) or were already retired (GPi n = 19, STN = 17) at baseline (Supplemental Data IV).

Sexual desire seems slightly diminished after both GPi DBS (n = 56) and STN DBS (n = 56). Sexual satisfaction remained relatively stable as well as the number of times sexual intercourse was initiated (Supplemental Data V). Two patients in the GPi group ended a relationship in the year after surgery, and none in the STN group. Marital satisfaction of both patients and partners remained stable after both DBS procedures (Supplemental Data VI).

Discussion

This study provides evidence of no difference in psychiatric outcome between GPi DBS and STN DBS for PD. In addition, descriptive analyses show stable social functioning after DBS in both targets.

The choice between GPi DBS or STN DBS in advanced PD is still a source of controversy.[20] A trial by Anderson et al[5] reported more cognitive and behavioral adverse effects after STN DBS. This was a randomized controlled trial with a small sample size (GPi 10, STN 10). Our between-group comparison showed no evidence that psychiatric effects are different after GPi or STN DBS, which is in line with findings from a trial comparing DBS with best medical treatment[21] and findings from a comparison of unilateral GPi DBS and STN DBS.[22]

Within-group comparisons showed little change 12 months after surgery. Overall, the mania rating scores were very low at both points and thus were not indicative for mania. The results on the HADS indicated slightly higher subscale scores for anxiety than for depression, as has been reported before in 177 PD patients without DBS.[6] We found no change in scores after 12 months, suggesting a stable mood profile regarding anxiety and depression.

The positive affect scores also showed significant but small decreases in both groups, which can be considered negligible because scores at baseline and 12 months are within 1 standard deviation of healthy adults. Absolute changes on the character traits on the FFPI were also small, for example, 0.2 standard deviation for GPi DBS on extraversion, and therefore do not seem clinically relevant.

No observed increase in psychiatric disorders was seen after DBS in either target (MINI-interviews). This is an important confirmation that DBS is a safe procedure in PD from a psychiatric point of view.[21] The psychotic disorders observed in the 12 months after DBS were transient and mostly caused by medication. In our study, suicidal ideation seems not to differ between GPi and STN DBS, which has been reported before.[23] No suicide attempts occurred in our trial 12 months after surgery.

Sexual desire seems to be lower 12 months after both GPi DBS and STN DBS. Sexual satisfaction and number of monthly initiations of sexual intercourse seemed not to change after surgery. Based on these data, establishing an origin of the decline of sexual desire is not possible, but a decrease in dopaminergic medication could play a role. Although a negative effect of DBS on societal participation has been described,[1] our data shows stable participation and a stable number of friends. The stable marital satisfaction is an especially reassuring finding, because case reports have been published about relational issues after DBS.[1]

A caveat of this study is the missing data. The NSTAPS protocol was exhaustive for patients. Importantly, no difference was found in the amount of missing data between the groups, and the imputation analyses resulted in similar outcomes.

In conclusion, we did not find large differences in psychiatric and social effects between GPi DBS and STN DBS. Moreover, there was little deterioration over time. Thus, DBS in both the STN and the GPi seems a safe procedure for PD patients with respect to psychiatric and social outcome. Consequently, the decision for GPi DBS or STN DBS in individual patients cannot be based on expected psychiatric or social effects of these interventions. ■

Supplemental Data

Filename "Data Supplement NSTAPS Brief Report":

- data supplement I: Assessment of marital satisfaction
- data supplement II: Full data of the MINI psychiatric evaluation
- data supplement III: Data of the social activities questionnaire, work evaluation
- data supplement IV: Data of the social activities questionnaire, organizations
- data supplement V: Data on sexual desire, sexual satisfaction, and monthly initiations at sexual intercourse
- data supplement VI: Data on marital satisfaction of patients and partners
- data supplement VII: Patients showing decline on multiple measures in multiple domains

APPENDIX

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Supporting Data

Additional Supporting Information may be found in the online version of this article at the publisher's web-site.