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Subjective perceived outcome of subthalamic deep brain stimulation in Parkinson's disease one year after surgery

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ABSTRACT

Objectives: Dissatisfaction with subthalamic deep brain stimulation (STN-DBS) despite motor improvements has been observed in Parkinson's disease (PD). Hence, we compared patient's subjective perceived outcome 12 months after surgery (12mFU) with clinical measures to identify risk factors of dissatisfaction.

Methods: Patients were examined at baseline and 12mFU. Quality of life (QoL), neuropsychiatric, cognitive and neurological functioning was measured. Patients were classified concerning their subjective outcome (negative = dissatisfaction; mixed; positive = satisfaction) at 12mFU using semi-structured interviews. First, the three groups were compared concerning interview statements. Second, repeated measures ANOVAs with group as between-subjects factor were applied to find significant effects of time, group, or interaction. Third, binary logistic regression determined predictors of dissatisfaction.

Results: Of the 28 enrolled patients, 25% perceived their outcome as negative, 32.1% as mixed, and 42.9% as positive. Concerning interview statements, dissatisfied patients mentioned significantly less often improved QoL and reduced medication, and reported worsening of mental state, and social interaction. For the whole sample, significant improvement over time was found for motor functioning, daily dopamine dosages, and QoL. Apathy significantly worsened over time, but dissatisfied patients were overall more apathetic and depressed than the other groups. Significant interaction of group and time was identified for QoL, which only improved in the mixed and satisfied group. Finally, preoperative apathy and axial symptoms predicted dissatisfaction with STN-DBS.

Conclusions: Although motor symptoms and QoL improved in the whole sample, 25% of patients showed disappointment with STN-DBS. Especially apathy predicts dissatisfaction and should be considered preoperatively.

1. Introduction

Although bilateral subthalamic deep brain stimulation (STN-DBS) significantly improves motor symptoms and quality of life (QoL) in Parkinson's disease (PD) [1,2], up to 25% of operated patients may perceive their subjective perceived outcome as negative [3]. This finding raises ethical concerns, since dissatisfied patients, who do not subjectively benefit from an expensive invasive surgery with possible side-effects, question the procedure [4,5]. Hence, the preoperative selection of possible STN-DBS patients is delicate and only appropriate candidates should be operated on [6]. However, so

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far, the STN-DBS selection criteria substantially rely on studies that used standardized outcome measures examining motor functioning and questionnaire-based QoL [1,2], thereby possibly overlooking PD patient's subjective perspective of surgical outcome. Recently, this methodological procedure has been challenged and new outcome measures that combine standard quantitative methods and more individual qualitative approaches have been used to assess PD patient's experience and satisfaction with STN-DBS [3,4]. By applying this approach, in a previous analysis, we could demonstrate that negative perception of short-term STN-DBS outcome is associated with unrealistic expectations and neuropsychiatric state, particularly apathy and depression, even in patients who were good DBS candidates, and did not experience problems related to surgery or the device [3]. Further contributing factors to patient's disappointment are axial symptoms, such as falls, balance or speaking difficulties [7,8], which often remain unaffected by STN-DBS [6]. However, the first months after operation are usually accompanied by numerous ups and downs due to lesion effects, adjustment of dopaminergic medication, increasing stimulation parameters and behavioral accommodation to the new life situation [5,9,10].

So far, long-term follow-up interview data of subjective patient outcomes compared with clinical measures do not exist. Therefore, our primary goal was to analyze semi-structured interviews and to determine the proportion of PD patients that perceive their outcome as negative one year after STN-DBS surgery. Secondarily, we aimed to identify differences in clinical characteristics that contribute to subjective perception of outcome over time. In line with others [6,7] and our own work [3], we hypothesized that disappointment is determined by neuropsychiatric and axial symptom severity. Additionally, subjective perceived outcome and changes on standard QoL measures were compared. Finally, we exploratively sought to identify predictors that contribute to dissatisfaction with STN-DBS.

2. Methods

2.1. Patients, study design, and monitoring

Thirty PD patients were prospectively examined before (baseline) STN-DBS surgery at the Department of Neurology, University of Cologne, Germany. Twenty-eight patients were subsequently seen at 12 months (12mFU) after implantation. Two patients were lost to follow-up. One patient was explanted due to an infection of the device and one patient died after an accident, unrelated to the procedure (for details see Ref. [11]). Idiopathic PD was diagnosed according to the Queen's Square Brain Bank criteria [12]. Patients with dementia, severe psychiatric or additional neurological disorders, and patients with a history of neurosurgery were excluded from this study [3]. An expert panel of neurologists, neurosurgeons, psychiatrists and neuropsychologists approved DBS surgery for each patient, independently of study participation. Additionally, potential risks and side-effects were explained to each patient by the neurologist and the neurosurgeon in a preoperative consultation. In this context patients were instructed about motor symptoms likely to improve (such as tremor) and motor symptoms unlikely to improve (such as falls) under STN-DBS.

The study was approved by the ethics committee of the University Hospital Cologne and patients signed consent forms before study participation. The study is listed at the German Clinical Trials Register (DRKS-ID: DRKS0003221). An independent center for clinical studies (ZKS Cologne) audited the core data and confirmed high data quality.

2.2. Surgical procedure

DBS surgery was performed at the Department of Stereotaxy and Functional Neurosurgery, University Hospital Cologne. The coordinates of the STN were determined on fused images of a presurgical 1.5T MRI with a stereotactically performed CT. The final electrode position (electrode standard model 3389; Medtronic, Minneapolis, Minnesota, USA) was based on intra-operative microelectrode recordings and macroelectrode test stimulation in the awake patient. Intra- and postoperative stereotactic x-rays were fused with the preoperative stereotactic MRIs to control the final electrode position. Finally, the electrodes were connected to an internal pulse generator (Kinetra or Activa RC/PC; Medtronic, Minneapolis, Minnesota, USA) that was placed subclavicularly.

In order to analyze the position of electrodes, the individual anterior commissure – posterior commissure coordinates (x, y, z) of patients' electrodes were determined applying the STP3 software (Stryker Leibinger, Germany). The coordinates of the lowest electrode pole (left and right hemisphere) were used for statistical analyses. Additionally, the width of the third ventricle was measured relative to the midcommisural point to account for brain atrophy.

2.3. Interview assessment

Semi-structured interviews were performed at 12mFU with all patients concerning how STN-DBS influenced their symptoms and daily life, including subjective improvements and worsenings [3]. All interviews were recorded, transcribed and categorized by two independent raters (C.L. and N.H.) according to theory-based content analysis [13]. Categories were analyzed regarding subjective positive and negative changes due to DBS. As described elsewhere [3], all positive and negative statements were noted for each patient. Since this study focused on the subjective perceived outcome at 12mFU, all patients were grouped according to their perception at this point in time. The classification of a subjective perceived negative, mixed or positive outcome was accomplished by dividing the number of positive statements by the number of negative statements. Patients who perceived their subjective outcome as negative had at least twice as many negative statements as positive statements (quotient$\leq$.5; group-neg). Patients, who had a subjective positive outcome, stated at least twice as many positive changes than negative changes (quotient$\geq$2.0; group-pos). Patients with a quotient >.5 and < 2.0 were assigned to a group that perceived their subjective outcome as mixed (group-mix). Patients were also asked whether they would have consented to STN-DBS surgery, had they known their outcome at 12mFU.

2.4. Clinical assessment

Patients were assessed with the motor part of the Unified Parkinson's Disease Rating Scale (UPDRS-III; range 0–108; [14]) before surgery (baseline) and at 12mFU. At baseline this test was performed in the medication off-state (MedOff; at least 12 h absence of dopaminergic medication along with 72 h absence of long-lasting dopamine agonists) and in best medical on-state (MedOn; at least 200 mg or 1.5 times the first morning L-dopa dose). At 12mFU, patients were examined in the stimulation on, medication on condition (StimOn/MedOn). Due to many missing values and the restricted reflection of daily life motor functioning in the stimulation on, medication off condition, these scores were not used in the final analysis. The Levodopa equivalent daily dose (LEDD) was calculated [15]. In line with others [16], the UPDRS-III total-score was analyzed regarding more dopamine-responsive symptoms (subscore A: tremor, rigidity, bradykinesia, facial expression; range