Predicting Response to vALIC Deep Brain Stimulation for Refractory Obsessive-Compulsive Disorder

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ABSTRACT

Background: Deep brain stimulation (DBS) for treatment-refractory obsessive-compulsive disorder (OCD) is effective in half of patients, but also is invasive and labor-intensive.

Objective: Selecting probable responders beforehand would more optimally allocate treatment resources and prevent patients' disappointment. Some centers use clinical and demographic predictors to exclude patients from DBS treatment, but the evidence base remains uncertain.

Methods: This observational cohort study examined the association of baseline demographic and disease characteristics with a 1-year prospective course of OCD and depressive symptoms in a cohort of 70 consecutive patients who received DBS of the ventral anterior limb of the internal capsule (vALIC-DBS) for OCD according to *DSM-IV* or *DSM-5* criteria between April 2005 and October 2017. Baseline characteristics and symptom decrease were analyzed using Fisher exact tests and binary logistic regression to examine whether they could predict individual response (> 35% reduction in Yale-Brown Obsessive Compulsive Scale score and 50% reduction in Hamilton Depression Rating Scale score, respectively).

Results: Insight into illness was the only significant predictor of individual response, with a positive predictive value of 84.4%, while the negative predictive value was 44.0% ($b = 0.247$, $\chi^2_1 = 5.259$, $P = .022$). Late-onset OCD was associated with more symptom decrease ($\beta = -0.29$; 95% CI, −0.53 to −0.04; $P = .023$) and comorbid personality disorder with less symptom decrease over time ($\beta = 0.88$; 95% CI −0.29 to 1.47; $P = .004$), but they could not significantly predict vALIC-DBS response. A later age at onset, comorbid personality disorder, and insight into illness were associated with clinical outcomes after vALIC-DBS, but predictive values were not large enough to facilitate clinical patient selection.

Conclusions: Clinical and demographic factors cannot yet predict outcome and should not be used to exclude patients from treatment with vALIC-DBS. These first individual prediction analyses for vALIC-DBS response in OCD are important, given that some centers up until now still exclude patients based on clinical characteristics such as comorbid personality disorders.

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Deep brain stimulation (DBS) is an effective treatment for refractory psychiatric disorders, particularly obsessive-compulsive disorder (OCD).[1,2] Nevertheless, DBS is invasive and comes with a small risk of post-surgical complications and (reversible) side effects, such as cognitive complaints like problems with concentration, planning, and memory and transient hypomanic symptoms.[3] Moreover, DBS requires substantial investment from patients and clinicians, and up to 50% of patients do not profit substantially from DBS.[1,2] If we could select probable responders beforehand based on baseline characteristics predicting outcome, we would be able to more optimally allocate treatment resources.

Previous studies[4,5] suggested baseline characteristics in OCD that might be associated with response to DBS. Patients with depressive symptoms and the need for symmetry or perfectionism were less likely to respond to DBS. A later age at OCD onset and sexual or religious obsessions have been associated with better response to DBS.[2] Another study[4] reported that patients with good insight into illness were more often responders.

The numbers of patients included in the aforementioned studies were relatively small (maximum N = 24), which complicated the identification of response predictors due to limited power. Some results of previous studies were conflicting. For instance, Alonso et al[2] found that a higher age at OCD onset was associated with a better response to DBS, whereas Raymaekers et al[5] could not confirm this relationship. Moreover, previous studies did not investigate the predictive value of these baseline characteristics on response, which makes it hard to say whether these predictions can be used clinically.

In the present study, we examined the predictive value of baseline characteristics on DBS of the ventral anterior limb of the internal capsule (vALIC-DBS) in the largest single-center cohort of OCD patients with DBS worldwide (70 patients). On the basis of previous studies, we hypothesized that a higher age at OCD onset, lower level of depression, better insight into illness, presence of taboo obsessions (aggressive, sexual, or religious), and a higher need for symmetry and perfectionism are predictors of response to vALIC-DBS. First, we tested the association between these

Clinical Points

- Deep brain stimulation (DBS) is an effective treatment for patients with refractory obsessive-compulsive disorder, but the treatment is invasive and not all patients respond.
- Selecting probable responders beforehand would more optimally allocate treatment resources and prevent patients' disappointment.
- Clinical and demographic factors cannot yet predict outcome and should not be used to exclude patients from treatment with DBS of the ventral anterior limb of the internal capsule.

baseline characteristics and reduction of OCD symptoms following vALIC-DBS. In a secondary explorative analysis, we examined other potential predictors. Finally, we tested the individual predictive value of significant baseline characteristics.

METHODS

Patients

The present study reports findings from a cohort of 70 patients who received DBS for treatment-refractory OCD.[1] All consecutive OCD patients who received bilateral DBS of the vALIC between April 2005 and October 2017 were included. Inclusion criteria for DBS were a primary diagnosis of OCD (per *DSM-IV* or *DSM-5* criteria) with a duration of ≥ 5 years, significant functional impairments, and a score of ≥ 28 on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS).[7] Patients had to have failed to respond to cognitive-behavioral therapy (CBT) and pharmacotherapy comprising at least 2 selective serotonin reuptake inhibitors (SSRIs), including an augmentation trial with an antipsychotic, and clomipramine, all at maximal dosage during ≥ 12 weeks. Patients were implanted bilaterally with electrodes in the vALIC, according to standard stereotactic procedures (Medtronic model 3389 with 0.5-mm spacing between contacts). After DBS parameter optimization, an individual CBT program was added as part of treatment.[6] For more detailed information about inclusion and exclusion criteria and treatment protocol, see Denys et al.[1]

Study Procedure and Measurements

The medical ethical committee of the Amsterdam University Medical Centers assessed the study and concluded that no approval was required for this retrospective analysis. Patients consented to the usage of data. Effectiveness of DBS on symptoms of OCD was assessed using the Y-BOCS,[7] a clinician-rated scale with scores ranging from 0 to 40. Depressive symptoms were measured using the 17-item Hamilton Depression Rating Scale (HDRS).[8] Y-BOCS and HDRS scores were obtained by unblinded clinicians prior to implantation and monthly till up to 6 months after surgery. Last measurement was 12 months after DBS implantation.

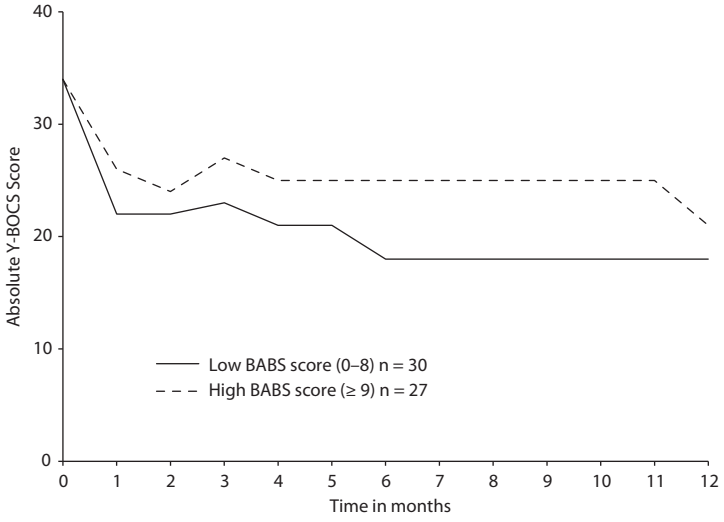
Data on demographic and baseline clinical characteristics were obtained prior to DBS surgery. OCD subtypes, including the "taboo" and "perfectionism and symmetry" subtypes, were assessed using the Yale-Brown Obsessive Compulsive Symptom Checklist (Y-BOCS-SC).[7] Insight into illness was assessed using the Brown Assessment of Beliefs Scale (BABS),[9] ranging from 0 to 24. A higher score on this scale indicates a poorer OCD insight and obsessions that have a more delusional character. We used the HDRS and the Hamilton Anxiety Rating Scale (HARS)[10] to assess symptoms of depression and anxiety, respectively, at baseline. Comorbid disorders were identified using the Structured Clinical Interview for *DSM-IV* Axis I and Axis II Disorders.[11,12] Functioning before DBS was assessed using the Global Assessment of Functioning (GAF).[13] Premorbid intelligence was estimated with the Dutch Adult Reading Test, the Dutch version of the National Adult Reading Test, which has proved to be a reliable test for premorbid

Table 1. Demographic Characteristics at Baseline of 70 Patients Treated With Deep Brain Stimulation for OCD[a]

Characteristic	Value
Sex, male/female, n	22/48
Age, mean (SD), y	41.7 (11.2)
Age at OCD onset, mean (SD), y	16.8 (8.7)
Duration of illness, mean (SD), y	25.0 (11.0)
Type of OCD symptoms, n (%)	
Fear of contamination and cleaning	30 (42.9)
Aggressive, sexual, and religious obsessions	6 (8.6)
Somatic obsessions and checking	1 (1.4)
Perfectionism, symmetry, and rituals	19 (27.1)
High risk assessment and checking	13 (18.6)
Comorbidity	
Major depressive disorder	30 (42.9)
Dysthymic disorder	2 (2.9)
Panic disorder with or without agoraphobia	4 (5.7)
Social phobia	2 (2.9)
Posttraumatic stress disorder	1 (1.4)
Eating disorder	3 (4.3)
Bipolar I disorder	3 (4.3)
Bipolar II disorder	1 (1.4)
Hoarding disorder	2 (2.9)
Somatization disorder	1 (1.4)
ADHD	1 (1.4)
Autism spectrum disorder	4 (5.7)
Obsessive compulsive personality disorder	7 (10)
Borderline personality disorder	1 (1.4)
Avoidant personality disorder	3 (4.3)
Unspecified personality disorder	3 (4.3)
Total with a mood disorder	36 (51.4)
Total with an anxiety disorder	7 (10.0)
Total with a personality disorder	14 (20.0)
Y-BOCS score, mean (SD)	33.7 (3.2)
HARS score, mean (SD)	25.4 (8.5)
HDRS score, mean (SD)	20.7 (6.4)
BABS score, mean (SD)	9.0 (5.6)
Functioning	
Premorbid IQ, mean (SD)	95.2 (11.8)
Civil status	
Single	25 (35.7)
In a relationship	41 (58.6)
Unknown	4 (5.7)
Employment situation	
Employed	13 (18.6)
Unemployed	57 (81.4)

[a]Values are shown as n (%) unless otherwise noted.
Abbreviations: ADHD = attention-deficit/hyperactivity disorder, BABS = Brown Assessment of Beliefs Scale, HARS = Hamilton Anxiety Rating Scale, HDRS = Hamilton Depression Rating Scale, OCD = obsessive-compulsive disorder, Y-BOCS = Yale-Brown Obsessive Compulsive Scale.

Figure 1. Y-BOCS Scores of OCD Patients With a Low or High BABS Score (Based on Median Split for Illustrative Purposes) During the First Year of Deep Brain Stimulation



Abbreviations: BABS = Brown Assessment of Beliefs Scale, OCD = obsessive-compulsive disorder, Y-BOCS = Yale-Brown Obsessive Compulsive Scale.

intelligence level.[14] Baseline variables that were missing were missing at random.

Statistical Analyses

Y-BOCS scores from baseline till 1-year follow-up were analyzed using linear mixed models (LMMs) with repeated Y-BOCS measurements being nested within patients. We chose LMM due to its ability to model data over time, allowing for the estimation of interaction effects between potential predictors and effects of stimulation and time.[15] We estimated a LMM with Y-BOCS score as the criterion and fixed effects of time and stimulation on subject-specific slopes. Time was expressed as time in months since DBS surgery and stimulation was a dichotomous variable (ON versus OFF). Selection of the covariance structure was based on the Akaike information criterion. The subject-specific slopes of the Y-BOCS were related to the following predefined baseline characteristics: age at onset, "taboo" and "perfectionism and symmetry" subtypes, baseline BABS score, and baseline HDRS score. As a secondary explorative analysis, we related the following baseline characteristics to the subject-specific slopes of the Y-BOCS: duration of OCD in years, age at surgery, sex, work status, relationship status, GAF score, presence of comorbid Axis I or 2 disorder, presence of comorbid obsessive-compulsive personality disorder or borderline personality disorder, presence of hoarding symptoms, premorbid IQ, and baseline HARS and Y-BOCS scores. As a second explorative analysis, we examined the relationship between baseline characteristics and the course of HDRS scores, using similar LMMs.

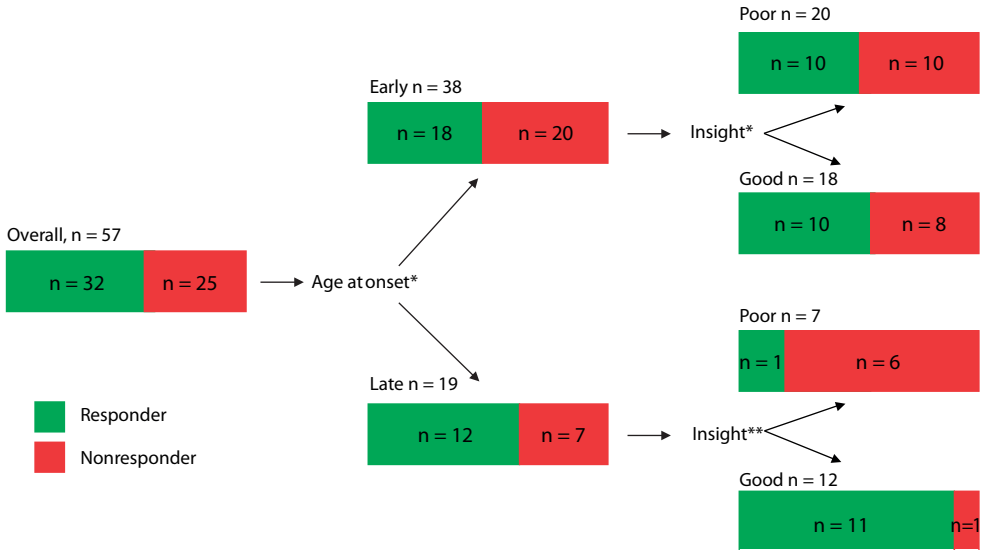
At 1-year follow-up, patients were divided into responders (Y-BOCS score reduction ≥ 35% compared to baseline) and nonresponders (Y-BOCS score reduction < 35% compared to baseline). We performed binary logistic regression analyses to identify which baseline characteristics could predict individual response to DBS. Only baseline characteristics that significantly interacted with stimulation or time were included in the binary logistic regression analyses. Response rates were also compared by Fisher exact tests (for analysis of 2 × 2 tables). Data are presented as the mean (SD) at a 2-tailed 5% level of significance. We used SPSS V24.0 to analyze our data (SPSS Inc; Chicago, Illinois).

RESULTS

More female (n = 48) than male (n = 22) patients received DBS (Table 1). The mean (SD) age of the population was 42 (11.2) years, and the mean age at OCD onset was 17 (8.7) years. The most prevalent OCD subtypes were "contamination fear" and "perfectionism and symmetry." Comorbidities included personality disorders (n = 14), mood disorders (n = 36), autism spectrum disorder (n = 4), and anxiety disorders (n = 7).

The LMMs showed that age at onset and insight into illness, as measured by the BABS, significantly interacted with effect of stimulation on Y-BOCS scores in patients for whom those data were available (n = 57). A later onset of OCD was associated with a larger Y-BOCS score decrease ($\beta = -0.29$; 95% CI, −0.53 to −0.04; $P = .023$). For every year of later OCD onset, Y-BOCS score decreased by 0.3 points more following DBS. Higher baseline BABS scores were related to less decrease of the Y-BOCS ($\beta = 0.49$; 95% CI, 0.07 to 0.90; $P = .021$, Figure 1). For every point a patient scored higher on the BABS at baseline, Y-BOCS score decreased 0.5 points less following DBS. The 2 OCD subtypes and symptoms of depression (HDRS score) at baseline had no significant effect on Y-BOCS scores over time.

Figure 2. Response Rate of 57 Patients Treated With Deep Brain Stimulation, Stratified by Age at Onset (Early Onset, ≤ 18 Years; Late Onset, > 18 Years) and Insight as Measured by BABS Score (Poor Insight, ≥ 9; Good Insight, ≤ 8, Based on Median Split for Illustrative Purposes) and Analyzed With Fisher Exact Test



*Nonsignificant.
**Significant ($P < .01$).
Abbreviation: BABS = Brown Assessment of Beliefs Scale.

Secondary explorative analyses showed significant interaction effects between presence of a personality disorder and stimulation ($\beta = -6.25$; 95% CI, −12.40 to −0.10; $P = .046$) and presence of a personality disorder and time in months ($\beta = 0.88$; 95% CI, −0.29 to 1.47; $P = .004$). Patients with a comorbid personality disorder initially showed a response to DBS in that their Y-BOCS scores would decrease by 6.25 points more following active stimulation compared to scores for patients without a personality disorder; across the duration of the study, however, their Y-BOCS scores decreased by 0.88 points less per month compared to scores for patients without a comorbid personality disorder. Other assessed factors did not interact significantly with the course of Y-BOCS scores during the first year of DBS. None of the examined baseline characteristics was significantly associated to HDRS scores following DBS.

After 12 months of DBS, 34 patients (49%) were nonresponders and 36 patients (51%) were responders. The predictive value of age at onset, baseline BABS score, and presence of a comorbid personality disorder were analyzed using binary logistic regression analyses. Only baseline BABS score was a significant predictor of response to DBS, with lower BABS scores predicting better response to DBS ($b = 0.247$, $\chi^2_1 = 5.259$, $P = .022$). The positive predictive value of baseline BABS score was 84.4% and the negative predictive value 44.0%. The overall predictive value was 66.7%. We controlled for potential covariates (disease severity and age at onset) using backward logistic regression. The response rate of late-onset OCD patients remarkably differed when dichotomizing by insight into illness as measured by the BABS (odds ratio = 66; 95% CI, 3.47 to 1,254.64; $P < .01$; Figure 2).

DISCUSSION

The current study investigated the predictive value of baseline characteristics to vALIC-DBS response in patients with treatment-refractory OCD. We found that patients with good insight and a later age at OCD onset had a higher chance to respond to vALIC-DBS. Patients with comorbid personality disorder had a good initial response, but their OCD symptoms decreased less over time than those in patients without a comorbid personality disorder. Other baseline characteristics were not related to response, for either OCD or mood. Only insight into illness could significantly predict response for individual patients; the positive predictive value was 84.4%, but the negative predictive value only 44.0%. Patients with late onset of OCD and good insight were the most likely to respond to vALIC-DBS, while patients with a late onset of OCD and poor insight were the least likely to respond. All in all, results suggest that, as of yet, baseline clinical characteristics cannot be used to reliably predict nonresponse to vALIC-DBS on an individual level in daily clinical practice.

In contrast to previous studies, in this largest study to date, we did not find that symptom dimensions or severity of depressive symptoms at baseline were associated with response to vALIC-DBS.[2,4,5] Nevertheless, we did find 3 baseline characteristics that were associated with response to vALIC-DBS, although the effects were relatively small. Good insight into illness correctly predicted response in 84.4% of cases, in line with our earlier finding.[4] The finding that an earlier age at OCD onset is associated with poorer vALIC-DBS response is also in accordance with previous

studies.[2] Good illness insight and later age at OCD onset are also associated with better response to pharmacologic treatment, so these baseline characteristics may not be specific for response to vALIC-DBS.[16,17]

Our findings show that patients with a comorbid personality disorder initially responded well to stimulation but profited less from the vALIC-DBS over time than patients without personality disorder. It is unclear why they profited less. One might hypothesize, however, that the intrarelational dynamics with the professional team (or family, system) is less favorable the hampering of an optimal therapeutic atmosphere by personality characteristics. It is often suggested that patients with comorbid personality disorder are less likely to profit from CBT,[18] but there is not yet enough evidence supporting this assumption to use it as an exclusion criterion.

Limitations and Strengths

The major limitation of the current study is that, although this is probably the largest vALIC-DBS cohort with OCD patients, the sample size was still relatively small for some baseline characteristics with an unequal distribution, such as personality disorders. A post hoc power analysis showed that with the current sample size and a power of 0.8, we would have been able to find an odds ratio of only 15.51 for personality disorders. Another limitation is the relatively short follow-up period of 12 months. In addition, most analyses were explorative, and we did not correct for multiple analyses to prevent type II errors. Finally, we predicted outcomes defined according to standard clinical symptom scales, while functional outcomes and quality of life may be more relevant for patients. Strengths of this study include the relatively large sample size for this field of research. In addition, the majority of the included patients received vALIC-DBS as a regular treatment, so the population closely resembled the population in a naturalistic clinical setting. This strength enhances the generalizability of our results to non-research patients.

Clinical Implications

Our finding that clinical variables do not predict nonresponse is important, given that some centers still exclude patients based on clinical characteristics such as comorbid personality disorders.[19] Our results provide no justification for clinicians' intuitive tendencies to exclude patients with a personality disorder. Given that the negative predictive value for response of the sole significant predictor, insight into illness, was only 44%, we advise against excluding patients from vALIC-DBS due to expected nonresponse based on clinical characteristics. Until reliable predictors for nonresponse have been found, patients with refractory OCD should not be denied vALIC-DBS based on baseline characteristics. We did find that patients with a late age at OCD onset and good insight in illness were especially likely to respond to vALIC-DBS. Although this outcome should not be used to include or exclude patients for vALIC-DBS, it can help clinicians to inform patients about their chances of response in the process of shared decision making. Nonetheless, the number of included patients was small, so results should be interpreted with caution.

Future Research

Larger samples may result in identification of more consistent clinical predictors. Use of patient-reported outcome measures may provide a better definition of response. To find reliable predictors, future studies can benefit from upscaling and technological advances. Machine learning can be used as a tool to combine multidimensional data about clinical characteristics, brain targets, and parameter settings and use that information for the prediction of treatment outcome to improve precision medicine in DBS. International cooperation and pooling of individual patient data can provide more power.

CONCLUSION

Our findings show that we cannot reliably predict nonresponse to vALIC-DBS based on OCD symptom dimensions or basic baseline characteristics. However, an older age at OCD onset and good illness insight were associated with better response to stimulation. Future models, including larger numbers of OCD patients, might improve prediction of response to DBS and facilitate personalized treatment. Until then, however, clinicians should stop excluding patients with refractory OCD from vALIC-DBS based on baseline clinical characteristics.

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