

Imaging-Guided Subthalamic Nucleus Deep Brain Stimulation Programming for Parkinson Disease

A Real-Life Pilot Study

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Abstract

Background and Objectives

Deep brain stimulation (DBS) is a well-established treatment for Parkinson disease (PD), with programming methods continually evolving. This study aimed to compare the efficacy and patient burden between conventional ring-mode programming (CP-RM) and image-guided volume of tissue activated (IG-VTA) programming for subthalamic nucleus (STN) DBS in PD.

Methods

In this retrospective study, patients with PD who underwent STN-DBS between 2011 and 2014 (CP-RM group) and 2019 and 2021 (IG-VTA group) were evaluated. The primary outcome was the improvement in the UPDRS III score from preoperative OFF to postoperative ON state without medication at one-year follow-up. Secondary outcomes included hospital stay duration and programming sessions.

Results

A total of 26 patients were analyzed (IG-VTA: n = 12, CP-RM: n = 14). Both groups showed similar improvements in UPDRS III scores (IG-VTA: 43.62, CP-RM: 41.29). However, the IG-VTA group experienced shorter immediate postoperative hospital stays and fewer hospitalizations after discharge.

Discussion

IG-VTA programming preserved the clinical efficacy of STN-DBS over 1 year and reduced the patient and clinician burden of hospital stay and programming sessions. However, conclusions drawn must consider the limitations of retrospective design, differing time epochs, and evolving clinical practices. Further multicentric and prospective studies are warranted to validate these findings in the evolving field of neurostimulation.

Trial Registration Information

The trial is registered on clinicaltrials.gov (NCT05103072).

Introduction

Bilateral deep brain stimulation of the subthalamic nucleus (STN-DBS) has emerged as an effective therapy for selected patients with Parkinson disease (PD) with intractable motor fluctuations.^{1,2} Traditionally, programming decisions aimed at achieving the best therapeutic response with minimal adverse effects were made through a time-consuming process known as conventional monopolar programming.³ This approach required multiple sessions, rendering the patient off medication and in the OFF condition throughout, incurring substantial hospital resources. Notably, in our practice in France, initial device adjustments are performed

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during a hospital stay, with subsequent adjustments generally conducted in outpatient settings. However, we also undertake scheduled hospitalizations at 3 and 12 months after surgery for comprehensive evaluations and device adjustments, reflecting a tailored approach to patient care and device optimization. Recent developments have introduced alternatives, such as the use of patient-specific volume of tissue activated (VTA) models based on DBS settings.^{4,5} Visualization systems like Guide XT (introduced by Boston Scientific in partnership with Brainlab) and SureTune (developed by Medtronic) combine patient-specific brain anatomy images with programmed stimulation parameters, generating personalized representations of the VTA.^{5,6} This allows immediate postoperative predictions of optimal contacts and stimulation parameters, eliminating the need for conventional programming. Studies have suggested correlations between VTA estimation at the STN's anatomical boundaries and motor adverse effects.⁶⁻⁹ While previous research has compared directional and omnidirectional stimulation, no studies have examined the clinical outcomes of patients programmed using image-guided VTA (IG-VTA) software vs conventional programming in the ring mode (CP-RM).¹⁰⁻¹³ The objective of our study was to determine whether patients with PD undergoing STN-DBS can achieve long-term motor improvement comparable with CP-RM patients by solely using IG-VTA software to select optimal contacts and stimulation parameters.

Methods

Study Design and Patient Cohorts

This retrospective study encompassed all patients with PD at Amiens University Hospital, France, who underwent bilateral STN-DBS using directional leads and software-based programming (Guide XT, Boston Scientific) for VTA estimation and optimal contact selection. The IG-VTA cohort consisted of patients treated from February 2019 to January 2021 while the historical control group underwent STN-DBS between March 2011 and February 2014 with standard CP-RM. Patients in both cohorts had advanced PD with motor fluctuations,

meeting CAPSIT-PD surgical eligibility criteria.¹⁴ Psychological and neuropsychological evaluations were conducted to ensure STN-DBS suitability, with patient consent as the only inclusion criterion. A visual representation of the patient care pathway for both cohorts is demonstrated in Figure 1, which illustrates the critical steps from the decision to operate, through DBS surgery, to postoperative evaluations at 3 and 12 months.

Standard Protocol Approvals, Registrations, and Patient Consents

We obtained approval to conduct this study through the Institutional Review Board (IRB) at the Amiens University Hospital, France (PI2021 843 0162). The trial is registered on clinicaltrials.gov (NCT05103072).

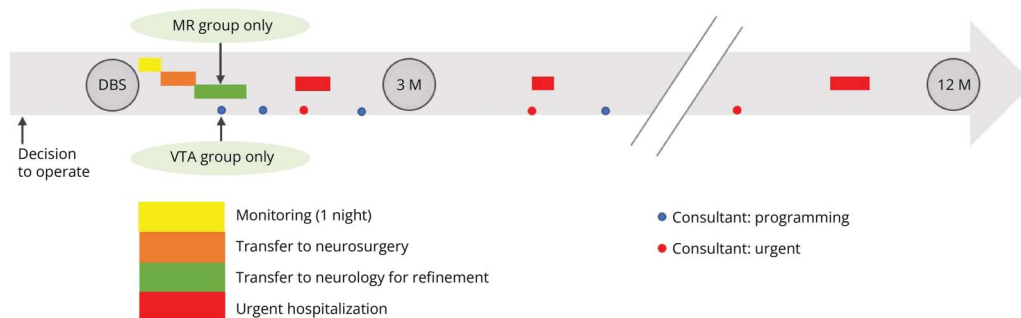
Surgical Procedure

All surgeries were performed by the same neurosurgeon (ML) under general anesthesia with the ROSA ONE Brain robotic platform (Zimmer Biomet).^{15,16} Preoperative imaging included MRI and CT scans, with intraoperative stereotactic CT scans (O-Arm, Medtronic) merged with preoperative MRI data. After lead implantation, macrostimulation and clinical analysis guided correct lead placement within the STN. Stimulation was conducted between contacts 2 and 3 to assess side effects, and final approval for implantation was granted if side effects occurred at an amplitude >3.5 mA and lead location within the STN was confirmed. If side effects were less than 3.5 mA or lead placement was outside the STN, a new trajectory was used. Octopolar directional leads (Vercise Cartesia, Boston Scientific) were implanted in the IG-VTA cohort while the CP-RM cohort received quadripolar unidirectional leads (Medtronic 3389 electrodes).

DBS Postoperative Programming

In the CP-RM cohort, neurologists sequentially stimulated each contact during the immediate postsurgery hospital stay to determine the contact with the widest therapeutic window (lowest effectiveness threshold and highest adverse effect threshold) with the patient in the OFF condition. In the IG-VTA cohort, the neurosurgeon and neurologist (both movement disorder experts) selected optimal contacts

Figure 1 Care Pathway in Patients With Parkinson Disease Undergoing Deep Brain Stimulation (DBS)



Therapeutic contacts and stimulation parameters were selected using either Guide XT to evaluate the patient-specific volume of tissue activated (VTA group) or conventional ring-mode programming (MR group).

postoperatively using VTA calculations and tailored them to the patient's clinical phenotype (e.g., laterality, symptom predominance, and dopaminergic psychosis history). With the help of the Guide XT module in the Brainlab Elements suite (Brainlab, Munich, Germany), the single contact or contact combinations facing in the direction of the dorsolateral STN were identified (Figure 2). While the initial targeting is facilitated by Guide XT software, crucial manual adjustments are made by the clinician to account for individual patient anatomical variations. This process is markedly expedited compared with traditional programming methods, typically requiring only a few minutes per patient to complete. The efficiency of this approach is attributed to the software's capability to provide a preliminary estimation of the VTA, which clinicians then fine-tune. Guide XT was used in the IG-VTA group not only during initial hospital-based programming sessions but also throughout subsequent outpatient consultations.

Outcome Measures

Patients underwent comprehensive assessments, including the Unified Parkinson's Disease Rating Scale (UPDRS) part III score under various conditions: on-stimulation/off-medication, off-stimulation/off-medication (worst OFF), off-stimulation/on-medication, and on-stimulation/on-medication (best ON).¹⁷ Motor evaluations helped assess dopamine sensitivity, stimulation effectiveness, and cumulative levodopa and stimulation effectiveness. In addition, patients completed preoperative evaluations using the Parkinson's Disease Questionnaire (PDQ-39), Mini-Mental State Examination, Hoehn and Yahr scale, and levodopa equivalent daily doses (LEDDs).¹⁸⁻²⁰

At 1 year postoperatively, stimulation parameters, consultation frequency, hospitalizations, and length of postoperative hospital stays (LOS) were evaluated. The primary outcome was the percentage improvement in the UPDRS III score between preoperative OFF state and postoperative on-stimulation/off-medication conditions at 1 year, with secondary outcomes including UPDRS IV, LEDD reduction, stimulation sensitivity, number of postoperative consultations, postoperative hospitalizations, and LOS.

Statistical Analysis

The demographic data between the 2 groups were compared using nonparametric tests like Fisher exact test or Mann-Whitney test, according to variable type. The comparison of preoperative and postoperative data was performed using the Wilcoxon test for quantitative data. The significance threshold (alpha risk) was set at 5% on bilateral tests. Any missing data were noted but not analyzed. All results were obtained using IBM SPSS Statistics 26.0 software. Results were presented as mean \pm SD for continuous variables or frequency (percentage) for categorical variables.

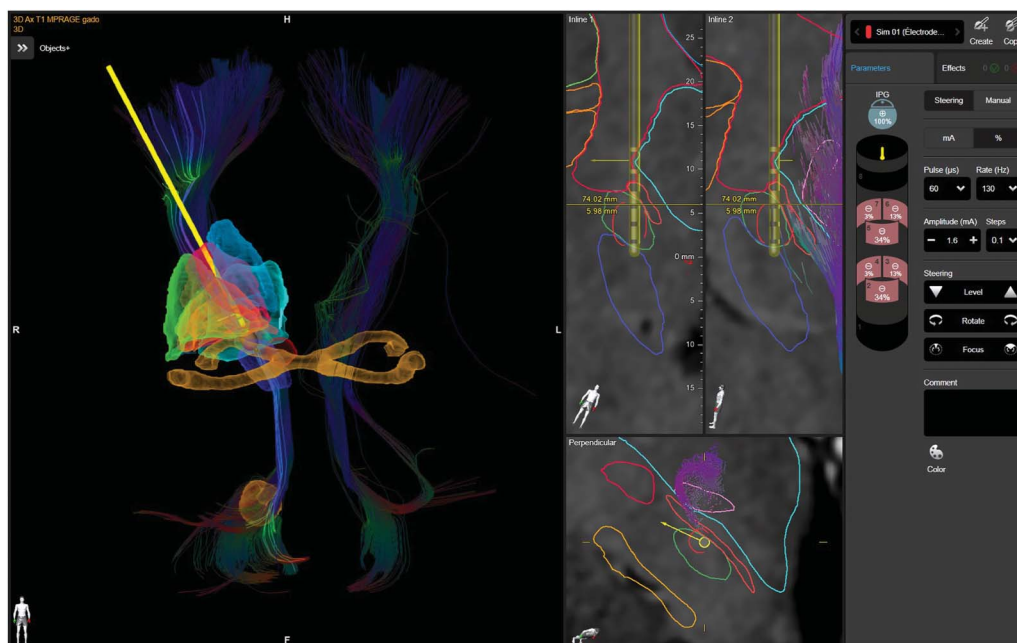
Data Availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available because of privacy or ethical restrictions.

Results

Twenty-six patients (15 men, 11 women) were included, with 12 in the IG-VTA cohort and 14 in the CP-RM cohort,

Figure 2 Example of VTA Programming of One of the Patients



with a mean age of 62.42 ± 7.55 years. A summary of patient characteristics is provided in Table 1, and the sole statistically significant difference between groups was a lower LEDD in the IG-VTA group ($p = 0.014$).

Both groups demonstrated significant improvement in UPDRS III scores, with an overall improvement of $42.46 \pm 19.17\%$ from the preoperative OFF state to the postoperative on-stimulation/off-medication condition at 1 year ($p < 0.0001$), as detailed in Table 2. It is important to note that there was no statistically significant difference in the percentage improvement between the IG-VTA and CP-RM groups ($p = 0.870$).

Table 2 provides a comprehensive overview of all secondary outcomes. While the IG-VTA group initially had a lower LEDD at 1 year than the CP-RM group, this difference was no longer statistically significant. Notably, the IG-VTA group exhibited a significant reduction in total LOS from surgery to 1 year, amounting to over 20 days less than that of the CP-RM group ($p < 0.001$). There was a significant decrease in hospitalizations after the POD in the IG-VTA group ($p = 0.007$). No other significant differences were observed in secondary outcomes.

All patients within the IG-VTA group achieved satisfactory outcomes with the initially selected programming strategy, and none required alternative programming approaches or transition to monopolar review during the follow-up period.

Discussion

The capacity to precisely target stimulation in PD has the potential to enhance patient outcomes, yet the increasing complexity of programming options has burdened conventional programming, making it time-consuming for both patients and clinicians.³ The integration of anatomy-based, image-guided visualization software has become indispensable in streamlining this process, albeit with uncertainties regarding its long-term impact.^{5,6,21,22} In our center, we adopted VTA estimation software in 2019 and previously demonstrated concordance in programming choices between the software program and CP-RM.⁶ This study proposes that long-term motor improvement remains unaffected when exclusively using IG-VTA software, for programming and fine-tuning stimulation. Both groups experienced significant and comparable motor symptom improvement

Table 1 Preoperative Patient Characteristics

	CP-RM (n = 14)	IG-VTA (n = 12)	Total (n = 26)	p Value ^a
Age at time of surgery (y)	63.31 ± 6.98	61.36 ± 8.35	62.42 ± 7.55	0.471
Sex, male/female (% female)	9/5 (36)	6/6 (50)	15/11 (42)	0.272
Duration of disease progression (y)	12.21 ± 3.46	12.08 ± 4.94	12.15 ± 4.12	0.698
UPDRS III (108 total score)				
OFF condition	35.5 ± 9.37	37.58 ± 12.56	36.46 ± 10.78	0.757
ON condition	14.71 ± 7.34	15.58 ± 8.57	15.12 ± 7.78	0.897
Levodopa sensitivity (% improvement in ON vs OFF condition)	59.32 ± 15.08	59.90 ± 13.27	59.59 ± 13.99	0.918
Axial subscore (20 total score)				
OFF condition	5.86 ± 2.65	9.00 ± 2.61	5.69 ± 2.58	0.980
ON condition	2.79 ± 2.33	3.00 ± 0.90	2.65 ± 1.79	0.631
UPDRS IV (24 total score)	6.57 ± 2.62	8.40 ± 5.02	7.05 ± 3.35	0.823
Hoehn and Yahr (5 total score)				
OFF condition	2.82 ± 0.61	2.67 ± 0.54	2.75 ± 0.57	0.725
ON condition	2.07 ± 0.51	1.88 ± 0.38	1.98 ± 0.46	0.190
MMSE (30 total score)	25.12 ± 1.80	26.67 ± 2.67	26.05 ± 2.44	0.065
PDQ-39 (%)	33.71 ± 19.61	35.99 ± 11.18	35.01 ± 14.96	0.286
LEDD (mg)	1,575.42 ± 476.42	1,199.18 ± 287.91	1,401.78 ± 437.14	0.014

Abbreviations: CP-RM = conventional, contact-by-contact programming in the ring mode; IG-VTA = imaging-guided VTA programming; LEDD = levodopa equivalent daily dose; MMSE = Mini-Mental State Examination; PDQ = Parkinson's Disease Questionnaire; UPDRS = Unified Parkinson's Disease Rating Scale; VTA = volume of tissue activated.

^a The significance threshold for the p value was set at 0.05. Data are expressed as mean ± SD unless otherwise indicated.

Table 2 Primary and Secondary Outcomes

	CP-RM (n = 14)	IG-VTA (n = 12)	Total (n = 26)	p Value ^a
UPDRS III				
Preoperative OFF	35.5 ± 9.37	37.58 ± 12.56	36.46 ± 10.78	0.757
On-stimulation/off-medication	19.63 ± 5.73	21.00 ± 10.35	20.32 ± 8.43	0.869
Off-stimulation/off-medication	33.83 ± 9.16	41.90 ± 12.59	37.69 ± 11.18	0.116
Off-stimulation/on-medication	15.08 ± 7.52	16.73 ± 7.75	15.86 ± 7.30	0.688
On-stimulation/on-medication	12.72 ± 6.71	10.90 ± 5.59	11.81 ± 5.90	0.621
Percent improvement on-stimulation/off-medication vs preoperative OFF (%)	41.29 ± 19.80 (<i>p</i> = 0.005)	43.62 ± 21.78 (<i>p</i> = 0.003)	42.46 ± 19.17 (<i>p</i> < 0.0001)	0.870
LEDD (mg)	492.00 ± 273.86	447.44 ± 223.34	491.10 ± 250.29	0.302
Reduction in LEDD (%)	67.38 ± 17.36	61.78 ± 18.21	63.67 ± 17.49	0.758
Stimulation sensitivity (%)	43.66 ± 9.20	49.86 ± 18.42	46.76 ± 14.57	0.131
Levodopa sensitivity (%)	56.38 ± 16.71	58.61 ± 15.89	57.45 ± 15.94	0.805
Overall improvement in levodopa and stimulation (%)	64.19 ± 16.24	73.85 ± 11.01	69.02 ± 14.42	0.123
UPDRS IV				
Duration between surgery and 1-y FU (mo), mean (range)	13.06 (11.25–18.84)	12.39 (9.17–18.61)	13.17 (9.17–18.84)	0.711
Immediate postoperative LOS (d)	18.93 (8–45)	6.25 (5–15)	13.15 (5–45)	<0.0001
Number of consultations between surgery and 1-y FU	6.57 (4–11)	7.08 (6–10)	7.46 (4–16)	0.875
Number of hospitalizations between POD and 1-y FU	2.00 (0–4)	1.17 (0–3)	1.73 (0–4)	0.007
LOS between POD and 1-y FU (d)	17.07 (4–53)	8.17 (4–17)	12.84 (4–53)	0.041
Total LOS between date of surgery and 1-y FU (d)	34.78 (17–66)	14.42 (9–27)	25.30 (9–66)	<0.001

Abbreviations: CP-RM = conventional, contact-by-contact programming in the ring mode; FU = follow-up; IG-VTA = imaging-guided VTA programming; LEDD = levodopa equivalent daily dose; LOS = length of stay; POD = postoperative discharge; UPDRS = Unified Parkinson's Disease Rating Scale; VTA = volume of tissue activated.

^a The significance threshold for the *p* value was set at 0.05. Data are expressed as mean ± SD unless otherwise indicated.

(69%), consistent with previous research. For instance, a review of 7 studies in bilateral STN-DBS patients under general anesthesia reported percentage improvements ranging from 25% to 66%.²³ In individual trials, improvements were reported at 49%, 19%, and 40%.^{24–26} Of interest, VTA software programming had a beneficial impact on our patient care pathway, resulting in significantly reduced hospitalizations and shorter stays compared with CP-RM patients. The IG-VTA group exhibited over 12 days less postoperative stay on average. Hospitalizations in the CP-RM group were primarily driven by the need for DBS programming adjustments, suggesting that image guidance does not reduce the obtention of optimized initial settings. The use of VTA software facilitated a more efficient optimization of stimulation settings compared with CP-RM. This efficiency stems from the fact that standard monopolar reviews, although thorough, require a significant investment of time to manually test and adjust each electrode

contact. Notably, the use of VTA software offers real-time visualization of lead placement, which is crucial for accurate programming decisions tailored to the individual patient. VTA software may enhance programmer confidence by providing comprehensive patient-specific data before programming initiation. It ensures rapid accessibility to patient information for the entire medical team, promoting effective care continuity and settings verification.

While our findings suggest similar clinical effectiveness between these approaches, several key limitations and contextual considerations merit discussion:

- First, the inclusion of patient groups from different time periods (2011–2014 and 2019–2021) raises concerns regarding variations in clinical and economic practices over these time periods. The evolution in clinical

management and technologic advancements during these periods may have influenced patient outcomes. Recognizing this, our conclusions about the efficacy of IG-VTA should be viewed with caution, considering the potential impact of these external factors.

- Second, the comparison of IG-VTA with CP-RM programming might not fully account for advancements in knowledge and practice within the field over time. The potential learning curve and increased familiarity with DBS technologies could have influenced patient outcomes, a factor not directly addressed in our study.
- Third, the differences in implant technologies (octopolar directional vs quadripolar unidirectional) and stimulation parameters between the 2 groups might have introduced a bias in our analysis.
- Fourth, while VTA software provides an invaluable tool, it is essential to recognize that the VTA remains a model, albeit an inexact representation.^{4,5} In addition, VTA software relevance is greatly dependent on the MRI image quality such as in spatial resolution and contrast resolution to embrace the anatomical structures and its environment in the 3 planes of space.²
- Finally, we acknowledge the limitation related to the lack of detailed programming parameter data for all patients in the IG-VTA group, due to missing information inherent in the retrospective nature of our study. However, it is noteworthy that no IG-VTA group patients required conventional monopolar review reprogramming, and bipolar programming was not used. The predominant use of directional stimulation, based on Guide XT software, may introduce a bias when comparing with the CP-RM group programmed in the traditional ring mode. This aspect, although limiting, does not detract from the significance of our findings, demonstrating the feasibility and effectiveness of image-guided programming in clinical practice, as discussed in our analysis.

In light of these considerations, the conclusion of our study advocating the IG-VTA approach's benefits must be interpreted with an understanding of these limitations. Future studies with a more controlled design, possibly including prospective and

TAKE-HOME POINTS

- Image-guided DBS programming showed similar effectiveness to the traditional programming method.
- Patients receiving image-guided DBS programming had shorter hospital stays.
- Follow-up hospital visits were fewer for patients receiving image-guided DBS programming.
- Image-guided DBS programming reduced burden on both patients and clinicians.

multicenter approaches, are needed to validate our findings and address the ongoing debate about the potential inaccuracies in imaging registration and VTA estimation.

In conclusion, our study contributes to the growing body of evidence in support of image-guided programming in DBS yet underscores the necessity for continuous evaluation and refinement of these techniques in the rapidly evolving field of neurostimulation.

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Disclosure

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