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Original Article

Long-term follow-up of Parkinsonian patients operated on with deep brain electromodulation without intraoperative microrecording

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ABSTRACT

Background: Deep brain electromodulation (DBEM), also known as deep brain stimulation in different intracerebral targets, is the most widely used surgical treatment due to its effects in reducing motor symptoms of Parkinson's disease. The intracerebral microelectrode recording has been considered for decades as a necessary tool for the success of Parkinson's surgery. However, some publications give more importance to intracerebral stimulation as a better predictive test. Since 2002, we initiated a technique of brain implant of electrodes without micro recording and based solely on image-guided stereotaxis followed by intraoperative macrostimulation. In this work, we analyze our long-term results, taking into account motor skills and quality of life (QL) before and after surgery, and we also establish the patient's time of clinical improvement.

Methods: This is a descriptive clinical study in which the motor state of the patients was evaluated with the unified Parkinson's disease scale (UPDRS) and the QL using the Parkinson's disease QL questionnaire 39 questionnaires before surgery, in the "on" state of the medication; and after surgery, under active stimulation and in the "on" state.

Results: Twenty-four patients with ages ranging from 37 to 78 years undergoing surgery DBEM on the subthalamic nucleus were studied. An improvement of 41.4% in motor skills and 41.7% in QL was obtained.

Conclusion: When microrecording is not available, the results that can be obtained, based on preoperative imaging and clinical intraoperative findings, are optimal and beneficial for patients.

Keywords: Brain microrecording, Deep brain electromodulation, Deep brain stimulation, Image-guided implantation, Parkinson's disease, Parkinson's surgery, Quality of life,

INTRODUCTION

Deep brain electromodulation (DBEM), also known as "deep brain stimulation," is a surgical approach that offers multiple benefits for the symptoms of Parkinson's disease (PD), especially using the subthalamic nucleus (STN) as the target.[3,7,13,15,18] The use of intracerebral microelectrode recording (MER) has been established as a necessary tool to refine target location for decades.[4,12] However, some publications give more importance to intracerebral stimulation as a better predictive test,[16] so the use of cerebral MER during DBEM electrodes for PD has since become a subject of debate.[5,11] Since 2002, we initiated a technique of brain implant of electrodes without microrecording, based solely on image-guided stereotaxis implantation followed by intraoperative macrostimulation.[1,20] Although, in the beginning, it was for technical and economic reasons, we quickly observed that the results were quite reasonable, and we proceeded with it. In our opinion, MER was established as necessary because imaging technology was not sufficiently accurate in the earlier years. The intraoperative clinical tests with intracerebral stimulation, coupled with modern imaging technology, location of intracerebral targets can be as accurate and reliable as necessary. In fact, nowadays, some centers do not do any MER or intraoperative stimulation, with the targeting solely based on imaging.[21,23] The main objective of this research is to evaluate the long-term outcome of Parkinsonian patients, including the duration of improvement after surgery, operated on with DBEM in the STN, using an image-guided stereotaxys followed by intraoperative macrostimulation. Since the advent of MER, this is the first communication, as far as we know, on Parkinson's "awake" surgery without MER, based solely on imaging and clinical intraoperative findings.

MATERIALS AND METHODS

This is a clinical study with a descriptive design, in which a series of cases is analyzed to evaluate the effectiveness of DBEM, including the duration of improvement after surgery. The data were obtained directly from patients who underwent surgery from January 2009 to December 2017 in three different centers, all operated on by the same surgeon (SAS).

Patients had a diagnosis of PD of 5 years or more, of both sexes, aged between 40 and 80 years. The response to L-dopa (RL) was reported as a difference in the score (OFF-ON; absolute LR)[17] measured at the beginning of the disease and by the time of surgery. All of them had a reduced "on" period (compared to the "on" period at the treatment onset) of 21 points in the motor section (section III) of the unified Parkinson's disease scale (UPDRS) [10] and/or "on-off" fluctuations and/or dyskinesias. All patients underwent DBEM implants in the period from January 2009 to December 2017. Only those patients who could be fully followed up are included in the study. Those patients who could not have long-term follow-up or who suffered any complications were not included in the study. Contraindications to surgery were as follows: Lack of RL since the beginning of treatment; dementia or any cognitive disorder, and <5 years from PD diagnosis.

All the patients were informed about the purpose of the study, they were guaranteed complete confidentiality of the data obtained, and they gave their consent for inclusion in the study.

The surgical technique was already described elsewhere.[1,20] Briefly, the coordinates of the STN are calculated directly on the stereotactic magnetic resonance images (MRI). We do not use measures from the anterior commissure (AC) to the posterior commissure (PC); however, the MRI slices were parallel to the AC-PC line. The mathematical target of the system (center of the arc) is verified by intraoperative fluoroscopy. Electrical pulses of high (100 Hz) and low (5 Hz) frequency were applied by means of a test intracerebral electrode (Micromar3*, Sao Paulo, Brazil), with increasing intensity (0.5–9.0 volts). A neurologist monitored the changes in motor symptoms in the awake patient. Once the desired results are obtained, the definitive electrodes are implanted intracerebrally. After intubation and full anesthesia were given to the patient, the electrodes were connected to the pulse generator, which was placed subcutaneously in the right upper abdominal quadrant. The mean duration of the operative part of the surgery was four h. The DBEM systems used in this work were Soletra3®, Activa SC3®, Activa PC3® or Activa RC3® (Medtronic, Minneapolis, Minnesota, USA) and the STN was always the target.

Of 32 patients who underwent surgery, six could not be contacted to obtain a follow-up. One had the electrodes removed because he developed rejection and infection of the surgical scar (see complications in the Result and Analysis chapter). One did not consent to participate in the study. In total, our study is based on 24 patients.

The variables studied in each patient were motor skills and quality of life (QL). Motor skills were assessed using the motor UPDRS scale[6,10], which consists of 17 items that evaluate the presence or absence of limitations in certain motor areas.

QL was assessed through the Parkinson's disease QL questionnaire (PDQ-39).[19] There are 15 items grouped into six domains corresponding to daily tasks, independence, exercise, muscle discomfort, concentration, and emotionality. In each of the items, unfavorable situations of daily life were considered, which are scored from 0 (never present) to 4 (always present). The obtained results can add up to a total of 0–60 pts; the lower the score, the better the QL, and the higher the score, the lower the patient's QL.

Finally, an item called "subjective quality of life" was included, in which the patient was asked, "On a scale of 1–10, how do you feel about your QL?" both before and after the operation, thus evaluating how the patient feels according to their criteria.

The database was made using the Excel 2003® software, and for the data analysis, the EpiInfo 3.5.433® software. To compare the means before and after surgery of the motor values (motor UPDRS), QL (PDQ-39), and subjective QL, the paired Student's *t*-test was used, considering $P < 0.0001$ as significant in all cases.

Each variable was recorded at two times: Before surgery, in the "on" state, and after surgery, in the "on" state as well, and with the optimal programming of the DBEM system.

Follow-up was from 5 to 14 years, mean of 7.89 years.

RESULTS

Eleven (11) patients were women (45.83%), and 13 were men (54.17%), with ages ranging from 45 to 78 years (mean of 63.72) at the time of surgery [Table 1].

The time of disease was 09–22 years (mean of 15.25). The postoperative follow-up was from 5 to 14 years (mean of 7.89) [Table 1].

In the preoperative assessment, the motor UPDRS scale score ranged from 24 to 59 points (mean of 40.7 points), and in the postoperative, from 2 to 57 points (mean of 15.63 points), achieving an improvement of 2–41 points with an average of 22.4 points ($P < 0.0001$) [Table 1].

The results of these patients in terms of motor improvement were as follows: excellent in 10 patients (42%), marked in 4 (17%), moderate in 9 (37%), and poor in 1 (4%).

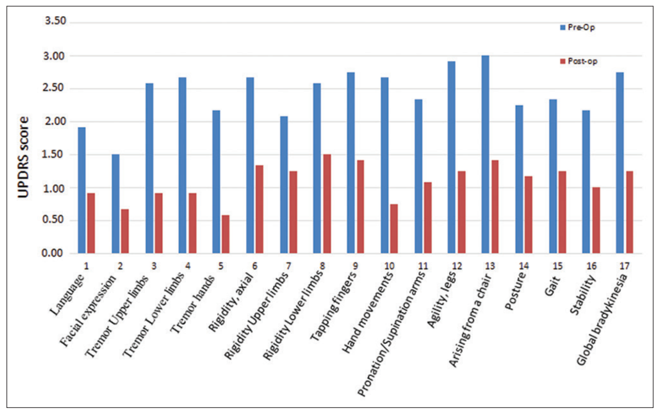
Table 1: Characteristics of the patient groups.

Variable	Range	Mean±SD	Mean difference
Age at Op (in years)	45–78	63.72±9.41	
TE PD (in years)	9–22	15.25±3.93	
Postoperative follow-up (yrs)	5–14	7.89±1.29	
UPDRS preoperative	24–59	40.70±10.78	22.40
UPDRS postoperative	2–57	15.63±12.57	*P*<0.0001
PDQ-39 preoperative	28–58	42.75±10.18	22.8
PDQ-39 postoperative	3–53	19.91±13.22	*P*<0.0001
QL preoperative	3–6	4.4±0.98	3.98
QL postoperative	4–10	8.38±1.71	*P*<0.0001

Op: Surgery, TE: Time of evolution of the disease before surgery, PD: Parkinson's disease, UPDRS: Unified Parkinson's disease rating scale, PDQ-39: Parkinson's disease quality of life questionnaire, QL: Subjective quality of life, SD: Standard deviation. The time of disease was 09–22 years (mean of 15.25). The postoperative follow-up was from 5 to 14 years (mean of 7.89). The preoperative assessment, the UPDRS scale score ranged from 24 to 59 points (mean of 40.7 points), and the postoperative, from 2 to 57 points (mean of 15.63 points), achieving an improvement of 2–41 points with an average of 22.4 points (*P*<0.0001)

Preoperatively, the highest scores in motor parameters were as follows: standing up from a chair ("arising from a chair," mean 3 points; standard deviation [SD]: 0.95), agility in the lower limbs (mean 2.92 points; SD: 0.9), movement (bradykinesia) and finger tapping (both mean 2.75 points; SD: 0.8 and 1.42, respectively), axial rigidity, alternating movements ("pronation/supination arms"), and tremor in the lower limbs (average 2.67 points; SD 0.98, 1.07, 1.15, respectively). A significant reduction in their score was subsequently achieved postoperatively, between 48.4% and 71.8% [Graph 1].

The motor parameters that had the highest percentage of postoperative improvement were as follows: hand tremor (73.0%), alternating movements with the hands ("pronation/supination arms," 71.8%), and leg (65.6%) and arm (64,5%) tremor [Graph 1]. However, it was the improvement in rigidity that gave the patients the best satisfaction.



Graph 1: Comparison of the mean of unified Parkinson's disease rating scale (UPDRS) score on motor symptoms before and after surgery. We can observe that all of them were reduced (improved). Preoperatively, the highest scores in motor parameters were as follows: standing up from a chair ("arising from a chair," mean 3 points; standard deviation [SD]: 0.95), agility in the lower limbs (mean 2.92 points; SD: 0.9), movement (bradykinesia) and finger tapping (both mean 2.75 points; SD: 0.8 and 1.42, respectively), axial rigidity, alternating movements ("pronation/supination arms"), and tremor in the lower limbs (average 2.67 points; SD 0.98, 1.07, 1.15, respectively). Postoperatively, a significant reduction in their score was subsequently achieved between 48.4% and 71.8%. The motor parameters that had the highest percentage of postoperative improvement were as follows: hand tremor (73.0%), alternating movements with the hands ("pronation/supination arms," 71.8%), and leg (65.6%) and arm (64,5%) tremor. The axial symptoms that were taken into account were Language, standing up from a chair ("arising from a chair"), posture, postural stability ("stability"), and gait. A preoperative score was obtained for these items, with a mean of 11.67 points (SD: 3.7) and a postoperative score of 5.75 points (SD: 5.81), achieving an average reduction (improvement) of 5.92 points (SD: 4.6), which represents a 50.71% improvement in axial symptoms after surgery.

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Regarding the analysis of QL, the preoperative PDQ-39 score ranged from 28 to 58 points (mean 42.75 points), and the postoperative was 3 to 53 points (mean 19, 91 points); thus, the average improvement was 22.8 points. The results of these patients in terms of improvement in QL were as follows: Excellent improvement in 11 patients (46%), marked improvement in 5 (21%), moderate improvement in 6 (25%), and poor improvement in 2 individuals (8%) [Graph 2a]. The characteristics of the QL that had the greatest improvement were emotionality (66.40%), self-sufficiency (61.59%), and the performance of daily tasks (39.84%) [Graph 2b].

In the subjective evaluation of QL, where 10 is the best score as QL according to the personal opinion of the patient, we found a preoperative score that ranged from 3 to 6 points (mean 4.5 points) and postoperative from 4 to 10 points (average 7.41 points) with an average improvement of 2.91 points.

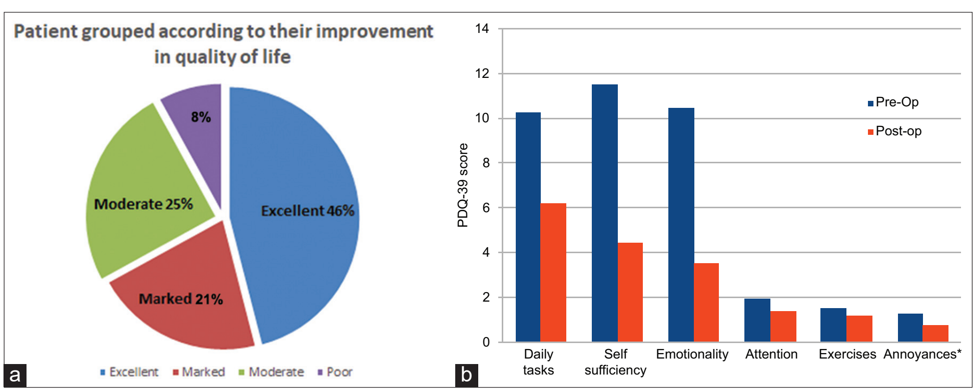
Regarding the time of postoperative motor improvement, it varies among the patients, and it was compared with the degree of improvement. In Table 2, it is shown the mean time of each group of improvement (of been good, improved), in which it is noted that the shorter time of being improved was on the "poor" improvement group [Table 2]. Regardless of the number of patients, we also considered the maximum time to be improved. An excellent improvement was maintained for a maximum of 11 years, marked improvement for 10 years, moderate improvement for 8.83 years, and a poor improvement for five years. The QL was maintained as follows: excellent improvement for a mean of 11 years, marked improvement for 11 years, moderate for 11 years, and poor improvement for six years.

When relating the patient's age at the time of surgery to the motor improvement and QL groups, we did not observe a significant difference [Table 3].

As mentioned above, some patients had complications and were not included in this series. One of them had an infection beneath one of the burr-hole covers, which secures the lead. When we reoperated, the pus was extending deeper, so we had to remove that side of the whole system. After three months under antibiotics, we repositioned a new lead. The patient is recovering from her previous improvement. Another complication was a rupture of the intra-cerebral portion of one lead. We had to change it for a new one. Finally, another one consisted of an upward displacement of the lead, probably due to not having been properly secured with the burr-hole cover. We replaced it and properly secured it.

DISCUSSION

This study highlights the benefit of DBEM based on image-guided stereotaxys followed by intraoperative macrostimulation in PD patients who met the inclusion



Graph 2: (a) Patients grouped according to their improvement in quality of life (QL). Regarding the analysis of QL, the preoperative Parkinson's disease QL questionnaire-39 score ranged from 28 to 58 points (mean 42.75 points), and the postoperative was 3–53 points (mean 19, 91 points); thus, the average improvement was 22.8 points. The results of these patients in terms of improvement in QL were as follows: Excellent improvement in 11 patients (46%), marked improvement in 5 (21%), moderate improvement in 6 (25%), and poor improvement in 2 individuals (8%). (b) Patients were grouped according to their improvement in QL. Comparison of the mean QL aspects before and after surgery (*annoyances: Painful muscles rigidity, pain in joints). The characteristics of the QL that had the greatest improvement were emotionality (in 66.40%), self-sufficiency (in 61.59%), and the performance of daily tasks (in 39.84%).

Table 2: Mean and maximum time (in years) of postoperative improvement in motor and quality of life aspects.

Groups of improvement	UPDRS-III (motor)		PDQ-39	
	Mean	Maximum	Mean	Maximum
Excellent	3	11	3	11
Marked	3	10	3	11
Moderate	2,83	8.83	3	10
Poor	1	5	1.5	6

UPDRS: Unified Parkinson's disease rating scale, III part (motor aspect), PDQ-39: Parkinson's disease quality of life questionnaire. The results of these patients in terms of motor improvement were as follows: excellent in 10 patients (42%), marked in 4 (17%), moderate in 9 (37%), and poor in 1 (4%)

Table 3: Mean age at the time of surgery related to motor (UPDRS-III) and quality of life (PDQ-39) outcome was not significantly different.

Groups of improvement	UPDRS-III	PDQ-39
Excellent	53.25	53.6
Marked	57	57
Moderate	66.33	67.25
Poor	58	66

UPDRS: Unified Parkinson's disease rating scale, PDQ-39: Parkinsn's disease quality of life questionnaire

criteria used in this work. Similar to other studies,[8,13,18,22] our work evaluates, pre-and post-operatively, two key aspects in the evolution of the disease: Motor impairment and the impact on QL, and in addition, we included the duration of improvement after surgery.

The motor aspect was clearly the symptom that improved the most, showing an improvement in the motor UPDRS scores of approximately 48% attributable to the effect of the DBEM combined with pharmacological therapy ("on" + DBEM), compared to the initial motor state before surgery, under the effects of exclusive medication ("on"), and there was a significant difference. These results are similar to those shown in other publications using MER.[8,12,13,18,22]

Furthermore, patients with the best motor response to DBEM (42%) showed a better motor state after three years after surgery. These patients were between 45 and 57 years old at the time of surgery and the shortest time of the disease. However, these ages at the time of surgery did not show a statistical difference compared with older ages in our series. The rest of the patients showed a progressive decrease in improvement in the same follow-up time, had a longer time of disease, and had an older age, both at the time of surgery.

An improvement in axial symptoms was observed in 50.71% of this study but did not last as long as the global motor skills improvement, assessed by the motor UPDRS scale. In another study, an improvement in axial symptoms has been reported as much as 45.4%.[6,7,13]

In regard to the QL, the aspects that showed the best improvement were emotionality (66.40%), self-sufficiency (61.59%), and performance of daily tasks (39.84%), which is also equivalent to other publications.[13,15,16,18] In general, 47% of patients reported having a better QL.

Regarding the subjective self-assessment of the QL, we also found a postoperative average improvement of 2.91 points. These results are similar to those shown in other publications using MER.[8,12,14,18,22]

The improvement of motor and neurobehavioral symptoms translates into results that have a favorable impact on improving the QL of patients.[14,19] PD continues its course despite the pharmacological and/or surgical treatment applied. In this context, it would be very useful to enhance the psychosocial support received by PD patients as well as their family members and caregivers to establish social guidelines that are more in line with their needs and that allow them to improve their quality of care and life further.

The present sample is small, and a larger series, with full follow-up, is necessary to determine the impact of DBEM using an image-guided stereotaxys followed by intraoperative macrostimulation in PD.

The use of MER goes back to the time when imaging was imprecise (i.e., ventriculography). Thus, adding MER increased the probability of reaching the target.[2] Furthermore, the use of the AC-PC line was by the time of ventriculography.[9] With the actual technology of the MRI, the nuclei are clearly visible, so we do not see the utility of using the inter-commissural line. The use of more sophisticated techniques of imaging, as, for example, the fusion of preoperative MRI with an intraoperative computed tomography scan, is in that line.[21,23] However, in view of the present work, reaching the target stereotactically based solely on the preoperative MRI and intraoperative macrostimulation is a reliable and effective method.

CONCLUSION

In conclusion, DBEM based solely on preOp imaging and clinical intraoperative findings is a treatment that offers as good results as those published with MER. In fact, there is now a tendency to use imaging as the only reference to locate the target, the STN.[21,23]

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Ethical approval

Approved by the Institutional Ethics Committee (IEC), letter HV20080612 dated 06/12/2008.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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