Annals of Neurosurgery

Ann Neurosurg., 2005; 6(1): 1-7

Bilateral subthalamic nucleus deep brain stimulation: the direct costs compared to the effects

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Aim: The aim of this study was to assess the direct cost of deep brain stimulation of bilateral subthalamic nucleus (DBS-STN) for Parkinson's disease in relation to its outcome.

Method: Direct costs and the effects of the DBS-STN treatment were evaluated in twenty successive Parkinsonian patients during a 12 months follow-up. The clinical effects on Parkinsonian symptoms were measured by the Unified Parkinson's Disease Rating Scale (UPDRS), and the effects on Health Related Quality of Life (HRQoL) were assessed using the Parkinson's Disease Questionnaire (PDQ-39) and the Nottingham Health Profile (NHP) as measuring instruments.

Results: STN DBS significantly improved the clinical symptoms and HRQoL of Parkinsonian patients. Incremental cost compared to preoperative medical treatment was calculated as 25 591 € (32 245 US$) per patient during the first postoperative year.

Conclusions: With acceptable incremental costs we were able to significantly relieve the motor complications of pharmacotherapy, resulting in a better functional outcome and increased quality of life for PD patients.

Key words:
Parkinson's disease ● subthalamic nucleus ● deep brain stimulation ● UPDRS ● HRQoL ● direct costs ● cost-effectiveness

Parkinson's disease (PD) is considered to be one of the most expensive neurological disorders [1] to treat. Especially the presence of motor complications resulting from pharmacological therapy is associated with high costs to the health care system [3]. Recently, there has been an increased interest in surgical procedures to treat advanced PD [2]. In particular, high frequency intracerebral stimulation of the subthalamic nucleus (STN) has become a realistic treatment option for severe Parkinson's disease in recent years [11]. Bilateral deep brain stimulation (DBS) of the STN has been shown to relieve cardinal motor signs in Parkinsonian patients [23, 1]. Furthermore, the need for medication decreases [20] and the quality of life improves [14, 9, 4) through long-term DBS-STN.

Despite the undisputable medical effectiveness of the DBS-STN treatment, the economic perspective must be taken into account in order to direct the available resources as sensibly as possible [24]. This is especially important when considering complex treatment modalities which may tie up a lot of health care system resources. So far, there is limited information about the costs compared to the effects of the STN DBS treatment [24, 26].

The aim of this study was to assess the direct costs of bilateral STN DBS in relation to symptomatic relief,

measured by the Unified Parkinson's Disease Rating Scale (UPDRS) [5], and health related quality of life (HRQoL), measured by the Nottingham Health Profile (NHP) [7] and the Parkinson's Disease Questionnaire (PDQ-39) [22] instruments.

Method

Twenty successive patients fulfilling the Parkinson's Disease Society Brain Bank clinical criteria, [6] and treated with bilateral STN stimulation, were evaluated preoperatively and during a 12 month follow-up using the UPDRS assessment as well as PDQ-39 and NHP instruments. The study was prospective, and patients were operated on between the years 2001 - 2003. The PD medication was stable for 3 months prior to the operation. Despite an optimal medication regime assessed and recommended by the treating neurologist, motor fluctuations, especially dyskinesias, were severe. The patients responded favourably to levodopa. The structure of the brain, visualised by MRI, was normal and every patient was evaluated by a neuropsychologist to exclude dementia and psychiatric disorders. The median preoperative Hoehn and Yahr staging was 3.

The patients (4 women and 16 men) with a mean age of (±S.D.) 59 ± 8 years had suffered from Parkinson's disease for a mean of (±S.D.) 13 ± 7 years.

Our surgical practice was comprised of a standard intraoperative ventriculography, serving as an anatomical basis for all stereotactic measurements. Intraoperative stereotactic X-ray control was routinely utilized for verifying the position of the implanted DBS-electrodes. Macrostimulation (Radionics RFG 5S stimulator, Radionics, Burlington, Mass.) combined with temporary test stimulation (Mattrix, Medtronic, Minneapolis) through permanent DBS electrodes (model 3387, Medtronic, Minneapolis) was also used. The STN was interpreted to be located 3 mm posterior to the midcommissural point, 5 mm below it and 12 mm lateral from the midline. The electrodes were implanted simultaneously. Beneficial effects, as well as indirect effects, were assessed during the test stimulation period. Thereafter, the following day, a permanent pulse generator (Kinetra, Medtronic, Minneapolis) was implanted under general anesthesia. Meticulous adjustments of the stimulation site and stimulation parameters were undertaken whenever needed during the follow-up. This was done in order to optimize DBS by striving to achieve maximum therapeutic potential with the least amount of possible side effects. The patient's medication was also carefully adjusted.

The effects of the DBS-STN on motor symptoms and the activities of daily life (ADL) were evaluated by our neurologist (TH) blinded to the stimulation status. The stimulator was randomized to be ON or OFF one hour before evaluation, which was performed twice. The patients were evaluated using the UPDRS part I (mentation, behavior and mood), part II (ADL), part III (motor subscale) and part IV (complications of therapy). The tests were performed preoperatively and then postoperatively at one and 12 months after the operation during the best medication-on phase. If necessary, the patients were invited to the hospital for additional visits for adjusting stimulation parameters.

We used two instruments, the PDQ-39 and NHP to measure health related quality of life (HRQoL). The PDQ-39 has a well established construct validity and a moderate content validity [8, 17]. The NHP is a generic instrument originally developed and tested for its validity and reliability in the UK [7, 18]. We used the first section of the authorized Finnish version of the NHP [10]. This ensures that the results are comparable with countries where the NHP has been validated.

This study assessed the direct costs, i.e. the costs of performing the operation and necessary postoperative care and follow-up visits, from the perspective of the health care provider. The costs were determined as the charges for drug treatment and the in-patient hospital care. The drug prices were attained from the official Finnish price list (Pharmaca Fennica, 2005) using the largest available package size. The costs of the surgery included the preoperative evaluations, operation theatre costs, salaries, anesthesia and the recovery room costs. The expenditure for a hospital day included all patient related costs such as treatment, examinations, drugs, food and physiotherapy. The prices were derived from the hospital register. The total cost for the hospital stay was calculated by multiplying the total number of days of hospital stay by the mean costs of one day. For implementing the DBS treatment, no new facilities had to be built in our hospital, as we could redirect the existing resources to this novel mode of therapy instead of traditional lesional stereotactic surgery.

All currency was converted according to the exchange rates of May 2005: € 1 = US$ 1.26.

All patients participated in the study voluntarily after

informed consent. The investigation received the approval of the local ethics committee.

For statistical treatment of the results, the SPSS-spreadsheet 12.0 was utilized. For statistical analysis of the results, Friedman's test and paired sample t-test were used. The level of significance was set at 0.05.

Results

The costs associated with DBS were divided into two categories: surgery and follow-up visits. The surgery costs included the stimulator, leads and electrodes (Kinetra, Medtronic, €14 346, US$ 18 076); salaries of the employees and use of the operation theatre plus the recovery room (€ 2 615, US$ 3 295); anesthesia (€ 1 380, US$ 1 739) and inpatient daily costs (€ 234, US$ 295/ day). The average length of stay for an operation was 7.9 days per patient, resulting in inpatient daily costs of € 1 849 (US$ 2 330). The surgery costs came to € 20 142 (US$ 25 379) per patient. On average there were three follow-up visits per patient during the first year after the treatment. The total length of the stay in hospital was, on average, 7.1 days per patient. Follow-up visits added a cost of € 1 661 (US$ 2 093) per patient. Thus, the total direct costs for the operative treatment per patient was € 25 869 (US$ 32 595) in the first year.

The patient's need for medication reduced significantly during the follow-up period; a mean daily dose of levodopa (± S.D) 450 ± 310 mg diminished to a mean dose of (± S.D) 320 ± 224 mg one year postoperatively ($p = 0.031$). Also, levodopa equivalent daily doses (LEDD) [27, 16, 12] reduced from 921 ± 459 mg to 779 ± 488 mg ($p = 0.007$). Our research also showed a significant decrease in mean drug costs during the follow-up (Table 3). The most important factor decreasing costs was the reduction of levodopa doses. The cost for drugs during the one-year period after the treatment was € 4 066 (US$ 5 123). Mean drug savings as a result of the operation totalled € 278 (US$ 350) in follow-up period costs per patient.

The clinical improvement of the patients is presented in Table 1. The most significant change was obtained in the UPDRS IV subscale values reflecting improvement of motor complications. At the end of follow-up period, the UPDRS subscale III (motor) score was (mean±S.D.) 25.1 ± 15.9 with stimulation on and 38.2 ± 18.2 with stimulation off ($p < 0.001$).

The effect of STN DBS on the HRQoL is presented in Table 2. Improvements in the PDQ-39 subscales for activities of daily life (ADL), emotional well-being, stigma, bodily discomfort and summary index were statistically significant. Only the PDQ-39 subscale communication values deteriorated significantly during the follow-up. In the NHP dimensions, there was a statistically significant improvement in sleep, emotional reactions and social isolation.

The total incremental cost, meaning the difference between the total direct costs of the operative treatment and the savings in medical costs during the same time, was calculated to be € 25 591 (US$ 32 245) per patient. Based on the UPDRS total score, the incremental cost per one unit improvement was € 1 815 (US$ 2 287). Incremental cost, using the PDQ-39 summary index as an outcome measurement, was € 3 083 (US$ 3 885) per one unit improvement.

Discussion

This study showed that STN DBS significantly relieves clinical symptoms and improves the HRQoL of Parkinsonian patients. The costs of bilateral STN DBS amounted to as much as € 25 869 (US$ 32 595) per patient during the one year follow-up period. The total incremental cost, meaning the difference between the total direct costs of the operative treatment and the savings in medical costs during the same time, was calculated to be € 25 591 (US$ 32 245) per patient. The first year of STN DBS therapy is expensive due to the high cost of the stimulator device. The following years are less expensive, because the stimulator only needs to be replaced after 3 – 5 years [11, 19].

The complications of medical therapy (UPDRS IV) diminished significantly resulting in a better functional outcome for the patients. This is also supported by a significant improvement in the ADL subscale (UPDRS II) values. Improvement in the HRQoL values using both the PDQ-39 and NHP instruments was obvious. The outcome of STN DBS, assessed with the UPDRS subscales with medication and stimulation on, was in the same range as that of other studies, which had an experimental design similar to ours [24, 21, 25]. The PDQ-39 measurements in our patient group showed a significant improvement in the subscales of ADL, emotional well-being, stigma and bodily discomfort.

In many previous STN DBS studies the effect of surgery is evaluated separately from that of medical treatment. Our decision to evaluate our patients with medication-on makes the comparison with many other studies difficult, but it realistically reflects the clinical outcome of the surgery. After all, the combined

Table 1. STN DBS effect on UPDRS (mean ± S.D., n=20). The patients were evaluated during the medication on phase.

UPDRS subscale	Baseline	1 Month	12 Months	*p*
UPDRS I (max. 16)	3.3 ± 2.2	3.2 ± 2.6	3.2 ± 2.7	0.948
UPDRS II (max. 52)	19.4 ± 5.8	14.8 ± 5.9	17.1 ± 8.4	0.005
UPDRS III (max. 108)	32.2 ± 14.7	27.2 ± 15.1	25.1 ± 15.9	0.130
UPDRS IV (max. 23)	9.9 ± 3.2	4.9 ± 3.1	5.4 ± 4.1	0.001
UPDRS total (max. 199)	64.9 ± 18.8	50.2 ± 22.7	50.8 ± 26.8	0.004

Friedman's test was used as a tool for statistical analysis.

Table 2. STN DBS effect on PDQ-39 and NHP (mean ± S.D., n=20)

	Baseline	1 Month	12 Months	*p*
PDQ-39 subscale (max. 100)				
Mobility	60.2 ± 16.7	50.2 ± 22.0	57.3 ± 20.4	0.402
ADL	64.0 ± 17.5	49.4 ± 22.3	49.4 ± 28.5	0.007
Emotional well-being	46.1 ± 16.4	33.9 ± 16.5	38.4 ± 19.1	0.034
Stigma	47.8 ± 25.2	32.6 ± 21.3	25.0 ± 21.1	0.003
Social support	33.0 ± 21.0	30.7 ± 20.7	34.5 ± 21.7	0.540
Cognition	33.9 ± 17.5	36.3 ± 22.9	31.7 ± 19.8	0.983
Communication	48.8 ± 22.6	42.3 ± 23.7	49.4 ± 31.8	0.010
Bodily discomfort	51.2 ± 21.4	34.5 ± 17.9	32.1 ± 24.4	0.011
PDQ-39 SI	51.3 ± 10.2	41.1 ± 16.0	43.0 ± 16.2	0.017
NHP subscale (max. 100)				
Energy	64.3 ± 34.9	64.1 ± 33.8	62.1 ± 33.5	0.937
Sleep	35.8 ± 26.5	20.7 ± 27.2	23.6 ± 30.4	0.025
Pain	69.4 ± 34.4	72.8 ± 34.8	78.5 ± 29.3	0.545
Emotional reactions	32.2 ± 29.1	19.1 ± 24.7	20.2 ± 22.8	0.027
Social isolation	30.7 ± 30.3	12.9 ± 19.6	22.1 ± 24.9	0.012
Physical mobility	64.8 ± 20.3	70.2 ± 27.8	63.8 ± 26.8	0.483

Friedman's test was used as a tool for statistical analysis.

Table 3. Mean drug costs before and 12 months after STN DBS, €

Drug	Baseline	12 Months
Levodopa	1.6±1.4 (n=20)	1.0±0.7 (n=18)
Levodopa CR	1.1±1.4 (n=11)	1.1±1.3 (n=11)
Dopamine agonist	3.7±3.9 (n=14)	3.3±3.7 (n=14)
Selegiline	0.4±0.9 (n=7)	0.4±0.9 (n=7)
COMT-inhibitor	5.2±3.6 (n=15)	4.8±3.5 (n=14)
Amantadine	0.01±0.06 (n=1)	0.01±0.06 (n=1)
Total per day	11.9±6.1 (n=20)	10.4±6.0 (n=20)a
Total per year	4343.6±2244.4 (n=20)	3787.7±2195.5 (n=20)a

*p<0.001 compared to baseline. A paired sample t-test was used for statistical analysis.

use of medication and stimulation is the ordinary postoperative state, and changes in that situation are meaningful to the patient. Also, the effect of surgery was demonstrated with the double blinded UPDRS motor score evaluation in both stimulation on and stimulation off conditions.

The direct costs of STN DBS (€ 25 869, US$ 32 595) were somewhat higher than in earlier studies [24, 19]: € 21 082 (US$ 26 563) and € 20 410 (US$ 25 712) for Spottke et al. and Meissner et al. respectively. The decrease in medical costs in our study was significant, even though the preoperative levodopa equivalent dose was already lower in our patients than in many other published series [24, 19, 25, 15]. Because the patients functioned as their own controls, we assumed that the medical costs of the patients would have been the same for a year without the operation.

One potential source of error of the calculations of the costs in this series is the omission of complications.

Due to the relatively high costs of the stimulator material and treatment of the eloquent brain areas, the complications might be very resource consuming, even if not common. Our group has performed altogether 86 DBS operation with 146 lead implantations during the years 1997-2004, and we have encountered only two major complications leading to mortality or morbidity. The eldest patient in our practice, a 74-year-old lady, died from a pulmonary embolism during the mobilization phase after otherwise uneventful DBS-STN surgery. Another patient with rapidly progressive and severe PD contracted a late postoperative intracerebral haemorrhage. This led to a permanent deterioration of her neurological status to the bedridden stage. This patient died 9 months postoperatively.

We stress, that this study applies to Finland, and may be extrapolated to countries of similar economic development. However, it is recommended that in every country the costs and the effects of STN DBS surgery should be studied and analyzed separately. Also, assessing the cost-effectiveness for the first year might give a false impression of the cost-effectiveness of DBS-STN when observed over many years. However, according to recent publications, the positive effect of STN DBS remains almost unchanged over years, but the costs are concentrated on the first year after the operation (11).

When formally estimating cost-effectiveness it is of course not adequate to analyze direct costs alone. Indirect costs such as the burden to health care and home care services should also be considered. Also, estimated life expectancies and the need to replace stimulators over time should be analyzed.

The decision model for life time cost-effectiveness of DBS surgery by Tomaszewski and Holloway [26] suggested that DBS surgery is clearly cost-effective if quality of life improves 18 % or more compared to those receiving best medical management. In the present series the direct costs of DBS surgery were somewhat lower than those in the model of Tomaszewski and Holloway [26]. Also, our clinical experiences indicate that the indirect costs estimated by Tomaszewski and Holloway are valid for our study as well. This allows us to compare changes in quality of life.

The subscale of the PDQ-39 instrument that is most responsive to DBS seems to be stigma (48 % improvement). Also, subscales of ADL (23 % improvement) and bodily discomfort (37 % improvement) clearly exceeded the threshold considered to be cost-effective. Even if the communication subscale worsened, the PDQ-39 summary index improvement was within the range of what is considered to be cost-effective in Tomaszewski's study. As for the NHP instrument, the dimension emotional reactions subscale was most sensitive (37 % improvement). Also sleep (34 % improvement) and social isolation (28 % improvement) subscales are clearly above the threshold considered to be cost-effective.

To conclude, with acceptable incremental costs we were able to significantly relieve the motor complications of pharmacotherapy resulting in a better functional outcome and an increased quality of life. However, when providing services by public insurance, the decision about relative cost-effectiveness remains as a subjective judgement, which has to be made within society.

Acknowledgements

This study was supported by a grant from the Finnish Parkinson Foundation and the Oulu Medical Research Foundation.

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Comment
The authors present a nice prospective study of 20 consecutive patients with advanced Parkinson's disease (PD) that underwent implantation of bilateral STN DBS devices. The costs of medical and overall treatment were analyzed and calculated relative to the degree of clinical improvement. The conclusions indicate that (1) STN DBS is effective in improvement of motor symptoms of PD, specifically the motor complications of its pharmacotherapy, as well as the quality of life for these patients; (2) despite reduction in medication requirements and associated cost savings, the surgery remains a very expensive approach – with incremental costs are higher than 25 000 € per patient; and (3) these costs are incurred despite respectable lack of complications and prolonged hospitalizations.

The study elegantly summarized the expenses related to the surgical and medical treatment of selected cohort of advanced PD patients. It assumed that medical care for the patient remains constant if they don't have surgery – and this may or may not be true considering that disease is progressive and most new drugs are more expensive than the ones that were used earlier. This assumption (of stability of medical costs) may underestimate the value of surgical intervention. Other limitations – and they were clearly identified by the authors – include difference in prices of medical and surgical treatments in different countries, significant change in cost of treatment related to prolonged hospitalizations of some patients and development of surgical (or medical) complications, as well as expenses related to functional deterioration and stay in assisted-living facilities.

Some of these issues will swing the balance one way and some – the other, and the only solution would be to follow a larger group of patients for a longer period of time, particularly since the cost of surgical group management (as the authors correctly noticed) will decrease after the first year and stay relatively low until the battery has to be changed or upgraded to a re-chargeable setup (which will be surely available within few years).

The best approach, obviously, would be to randomize patients into medical and surgical groups and follow them up prospectively – one may be surprised with high healthcare expenses that some of non-surgical patients will incur due to their advanced PD! Another option would be to find a comparable cohort of patients that for some reasons do not want to have surgery (but otherwise qualify for it) and follow them in parallel to the surgical group.

The authors should be congratulated with excellent outcomes and with impressive follow up and documentation of improvement. One of the things the article once again shows – great results may be obtained with different techniques (the authors use ventriculography but no microrecording; we use microrecording but no ventriculography; some groups, including Dr. Benabid in Grenoble, use both; whereas some others use neither), and the results are consistent.

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