



Debate:

DBS Utilization will

Expand in the Treatment of

PD in the Future

VA PD Consortium Meeting

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DBS: A Paradigm Shift in Treating PD is Beginning to Occur

- Neuromodulation has become an established approach to treating neurological disorders, especially movement disorders
 - 2002: FDA approval for STN & GPi DBS for PD
 - 2008: ~ 50,000 patients treated worldwide
 - >2000 scientific articles published on DBS



Factors That Favor Expanded Use

- A consistent approach to using DBS has emerged
- DBS provides rapid, robust, and persistent benefit to appropriately selected patients
- Only a minority of appropriate candidates have thus far been offered DBS
- Technological advances on the near horizon will lead to improved ease of use & even better outcomes
- More compelling treatments are not imminent



Consistency in Using DBS

- Patient candidacy criteria better established
- Surgical techniques more standardized and efficient
- Patient management algorithms established
- Methods of troubleshooting more effective
- Larger number of clinicians have developed expertise in DBS



DBS: Robust Motor Benefit

Pre-Op: February 2003

Off Meds



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DBS: Robust Motor Benefit

Post-Op: February 2004



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Off Meds, On Stim

DBS: Robust Motor Benefit

Post-Op: February 2006



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Off Meds, On Stim

Many Appropriate Patients Not Yet Offered DBS

Figure 7: Indicative PD patient number model for geriatric patient population

	2006	2007	2008	2009	2010	2011	2012	2013	2014
US									
Population (m)	303.9	310.0	316.2	322.5	329.0	335.6	342.3	349.1	356.1
Proportion of population over 60 yrs of age	11.2%	11.4%	11.6%	11.8%	12.0%	12.2%	12.4%	12.6%	12.8%
# of patients over 60 years of a age (m)	34.0	35.3	36.7	38.1	39.5	40.9	42.4	44.0	45.6
Incidence of PD in patients over 60 years of age	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%
Incidence of PD in patients under 60 years of age	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Number of geriatric PD patients (m)	0.31	0.32	0.33	0.34	0.36	0.37	0.38	0.40	0.41
Number of PD patients outside geriatric patient population	0.81	0.82	0.84	0.85	0.87	0.88	0.90	0.92	0.93
Total number of PD patients (m)	1.12	1.14	1.17	1.20	1.22	1.25	1.28	1.31	1.34
Proportion of PD patients with mild disease	30%	30%	30%	30%	30%	30%	30%	30%	30%
Proportion of PD patients with moderate-severe disease	44%	44%	44%	44%	44%	44%	44%	44%	44%
Proportion of PD patients with severe disease	25%	25%	25%	25%	25%	25%	25%	25%	25%
# of mild PD patients (m)	0.33	0.34	0.35	0.36	0.37	0.38	0.38	0.39	0.40
# of moderate-severe PD patients (m)	0.49	0.50	0.51	0.53	0.54	0.55	0.56	0.58	0.59
# of severe PD patients (m)	0.28	0.29	0.29	0.30	0.31	0.31	0.32	0.33	0.34
% of mild PD patients not adequately controlled by current therapies	15%	15%	15%	15%	15%	15%	15%	15%	15%
% of moderate-severe PD patients not adequately controlled by current therapies	37%	37%	37%	37%	37%	37%	37%	37%	37%
% of severe PD patients not adequately controlled by current therapies	70%	70%	70%	70%	70%	70%	70%	70%	70%
# of mild PD patients not adequately controlled by current therapies (m)	0.05	0.05	0.05	0.05	0.06	0.06	0.06	0.06	0.06
# of moderate-severe PD patients not adequately controlled by current therapies (m)	0.18	0.19	0.19	0.19	0.20	0.20	0.21	0.21	0.22
# of severe PD patients not adequately controlled by current therapies (m)	0.20	0.20	0.20	0.21	0.21	0.22	0.22	0.23	0.23

➔ ~190,000 moderate-severe patients in U.S. deemed inadequately controlled by current medical therapies

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Many Appropriate Patients Not Yet Offered DBS

Europe									
Population (m)	310.1	316.3	322.7	329.1	335.7	342.4	349.3	356.3	363.4
Proportion of population over 60 yrs of age	11.2%	11.4%	11.6%	11.8%	12.0%	12.2%	12.4%	12.6%	12.8%
# of patients over 60 years of a age (m)	34.7	36.1	37.4	38.8	40.3	41.8	43.3	44.9	46.5
Incidence of PD in patients over 60 years of age	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%
Incidence of PD in patients under 60 years of age	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Number of geriatric PD patients (m)	0.31	0.32	0.34	0.35	0.36	0.38	0.39	0.40	0.42
Number of PD patients outside geriatric patient population	0.83	0.84	0.86	0.87	0.89	0.90	0.92	0.93	0.95
Total number of PD patients (m)	1.14	1.17	1.19	1.22	1.25	1.28	1.31	1.34	1.37
Proportion of PD patients with mild disease	34%	34%	34%	34%	34%	34%	34%	34%	34%
Proportion of PD patients with moderate-severe disease	41%	41%	41%	41%	41%	41%	41%	41%	41%
Proportion of PD patients with severe disease	25%	25%	25%	25%	25%	25%	25%	25%	25%
# of mild PD patients (m)	0.39	0.40	0.41	0.41	0.42	0.43	0.44	0.45	0.47
# of moderate-severe PD patients (m)	0.47	0.48	0.49	0.50	0.51	0.52	0.54	0.55	0.56
# of severe PD patients (m)	0.28	0.29	0.30	0.31	0.31	0.32	0.33	0.33	0.34
% of mild PD patients not adequately controlled by current therapies	3%	3%	3%	3%	3%	3%	3%	3%	3%
% of moderate-severe PD patients not adequately controlled by current therapies	38%	38%	38%	38%	38%	38%	38%	38%	38%
% of severe PD patients not adequately controlled by current therapies	68%	68%	68%	68%	68%	68%	68%	68%	68%
# of mild PD patients not adequately controlled by current therapies (m)	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
# of moderate-severe PD patients not adequately controlled by current therapies (m)	0.18	0.18	0.19	0.19	0.19	0.20	0.20	0.21	0.21
# of severe PD patients not adequately controlled by current therapies (m)	0.19	0.20	0.20	0.21	0.21	0.22	0.22	0.23	0.23

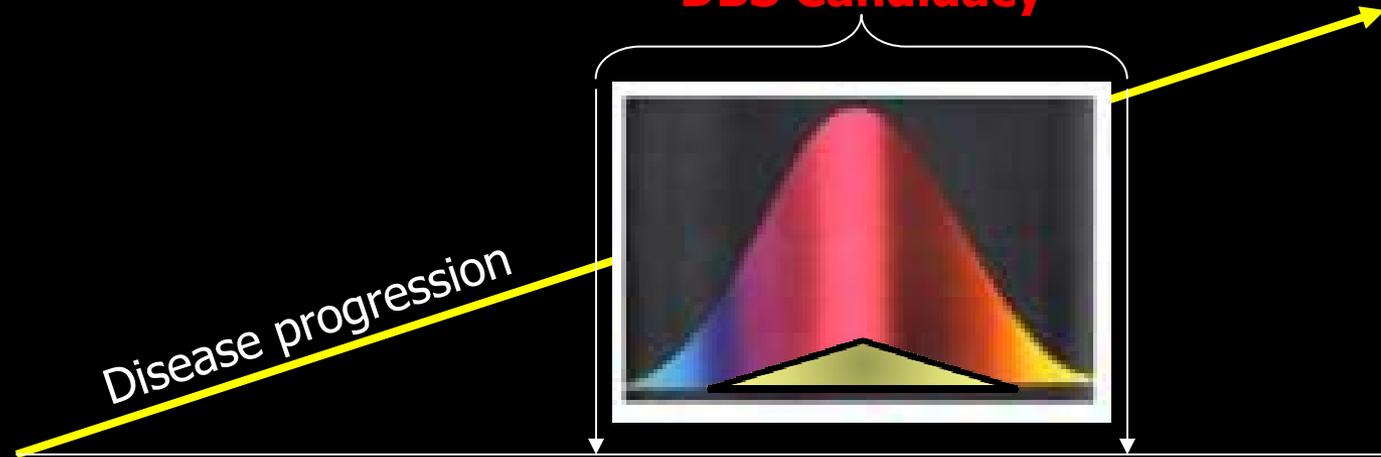
→ ~190,000 moderate-severe patients in Europe deemed inadequately controlled by current medical therapies

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DBS Candidacy



	Asymptomatic	Mild	Moderate	Severe
Symptoms:				
Issues:	None	Basic motor symptoms, mild-moderate disability	Motor complications (wearing off, dyskinesia, fluctuations), increasing disability, medication adverse effects	Severe motor impairment, dementia, non-motor symptoms, significant disability, intolerance of meds
Treatment:	N/A	Monotherapy when possible: agonists; amantadine; selegiline; levodopa when needed	Polypharmacy: agonists, levodopa, COMT inhibitor, amantadine, others	Levodopa
Drug success:	N/A	Usually excellent	Diminishing duration of symptom control for many	

DBS: Technological Advances Improve Ease & Outcomes

- **Present**: Patient selection tool: leverages expert experience & RAND appropriateness methodology to improve quality of patient referral; new targets being studied
- **Soon**: New devices available to meet patient & clinician needs; VA CSP#468 results available
- **Future**: Charge steering, MRI compatibility, brain & body activity sensing



Other Robust Treatments Unlikely to be Available Soon

- Symptomatic
- Disease-modifying



Conclusions

- DBS provides robust, relevant, and tailored treatment of motor symptoms for appropriately selected PD patients
- Use of DBS will likely expand and remain an important treatment option for many years

