Use of Rechargeable DBS Implantable Pulse Generators in Patients with Movement Disorders: Patient Satisfaction and Stimulation Parameters

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BACKGROUND

- Activa RC (Medtronic Inc; Minneapolis, MN) - first rechargeable (RC) dual-channel IPG for DBS approved by FDA in May 2009
  - Offers practitioners wider range of programming possibilities than older IPGs (e.g. interleaving)
  - Offers patients more control over DBS therapy (multiple groups, parameter adjustment within pre-set range)
  - Advertised battery life is 9 years
  - Particularly useful in patients who require high-energy stimulation and faster depletion of non-RC IPGs (e.g., GPI DBS in dystonia, TS)
  - Thinner profile than other IPGs (e.g., Soletra, Kinetra, Activa PC)

- To date, there are no evidence-based guidelines for DBS parameters adjustment after conversion of non-RC to RC IPG to help guide the practitioners in their care of patients with DBS
- To date, there are no reports of satisfaction with RC as initial therapy and after conversion from non-RC in patients with different movement disorders

METHODS

- Patients with RC placed as the initial device or converted from non-RC were identified from our DBS database
- All patients with RC IPGs were invited to participate in a phone survey:
  - Overall satisfaction with initial, non-RC IPG (scale 1 to 10)
  - Overall satisfaction with Activa RC IPG (scale 1 to 10)
  - Difference in symptom control between non-RC and RC IPG (scale 1 to 5; 3=equal)
  - Satisfaction with initial and RC IPG size (scale 1 to 5)
  - Simplicity of battery charging at home (scale 1 to 5)
  - Likelihood they would choose Activa RC again (scale 1 to 5)
  - Duration and frequency of battery recharging
  - Satisfaction with the information support and counseling received prior to discharge after RC implant (to avoid iatrogenic causes of dissatisfaction with RC)
- We compared patient satisfaction on various measures according to whether RC was placed as initial device or as replacement from non-RC.

- Retrospective chart review for patients converted to RC from non-RC
  - DBS parameters (amp, PW, frequency) before and after RC implantation were compared to assess return to pre-conversion settings
    - Last non-RC settings vs OR settings
    - Last non-RC vs RC settings at the end of 1st post-OR clinic visit
    - Last non-RC vs average of 3 first RC settings

RESULTS

Table 1. Patient demographic data

	Patient satisfaction survey (n=26)	Stimulation parameters comparison (n=14)	Total study participants (n=31)
Gender	14 M, 12 F	10 M, 4 F	18 M, 13 F
Age, yrs	15-90 (51.0 ± 18.79)	27-90 (57.14 ± 18.76)	15-90 (52.32 ± 17.84)
Diagnosis	7 dystonia 8 PD 6 ET 3 TS 1 RLS 1 myoclonus-dystonia	6 dystonia 3 PD 3 ET 2 TS	9 dystonia 9 PD 8 ET 3 TS 1 RLS 1 myoclonus-dystonia
DBS site	23 b/l (12 GPi, 6 VIM, 5 STN) 3 unilateral (1 GPi, 1 VIM, 1 STN)	12 b/l (9 GPi, 3 VIM – one had Δ'd electrode configuration on 1 side) 2 unilateral STN	28 b/l (14 GPi, 8 VIM, 6 STN) 3 unilateral (1 GPi, 1 VIM, 1 STN)
Initial RC vs conversion	9 initial 17 converted from Soletra	14 converted from Soletra	12 initial 19 converted from Soletra
Other	Survey conducted 1-25 mo after RC implant (12.12 ± 6.48)	25 electrodes from 14 patients analyzed	2-14 yrs after initial surgery (6.3 ± 3.44 yrs)

PD – Parkinson's disease, ET – essential tremor, TS – Tourette syndrome, RLS – restless legs syndrome
GPi – globus pallidus pars interna, VIM – ventral intermediate nucleus (thalamus), STN – subthalamic nucleus

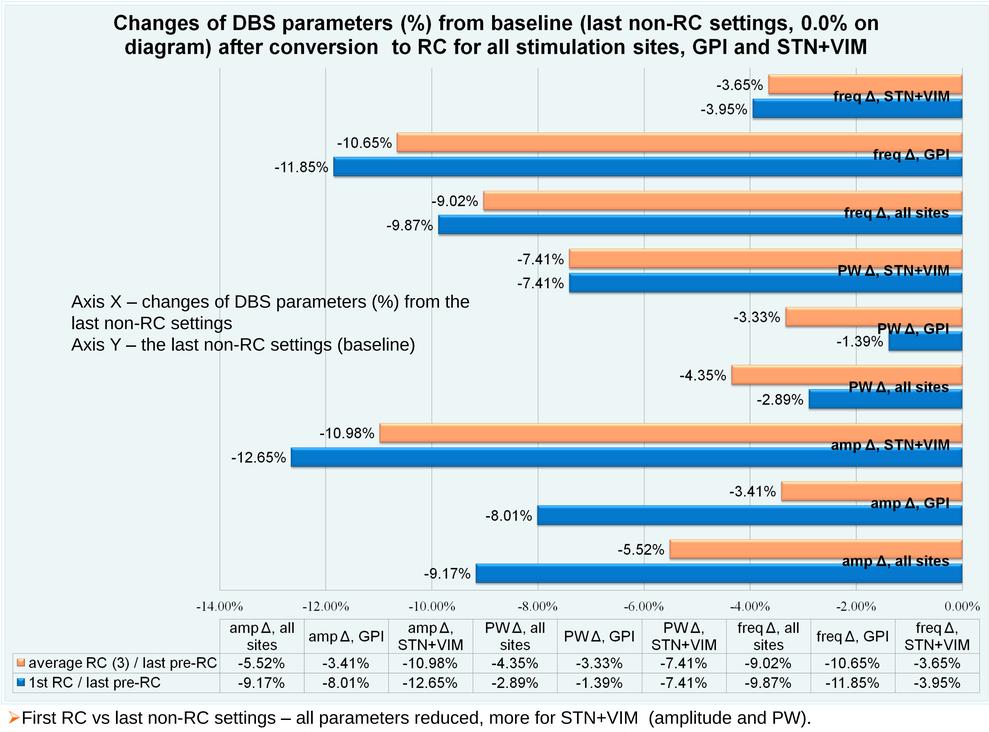
RESULTS (continued…)

Table 2. Patient satisfaction with rechargeable IPG

	Initial RC IPG (n=9)	Converted to RC IPG (n=17)	All patients (n=26)
Overall satisfaction with initial DBS device (scale 0-10)	n/a	5.70 ± 2.76	
Overall satisfaction with RC DBS device (scale 0-10)	8.22 ± 2.98	7.71 ± 1.96	7.88 ± 2.27
Difference in symptom control between non-RC and RC DBS devices (scale 1-5, 3= no difference)	n/a	3.0 ± 0.71	
Simplicity of recharging device at home (scale 1-5)	4.89 ± 0.33	4.23 ± 1.03	4.46 ± 0.90
Satisfaction with the size of non-RC battery (scale 1-5)	n/a	3.24 ± 1.35	
Satisfaction with the size of RC battery (scale 1-5)	4.11 ± 1.17	3.94 ± 1.03	4.0 ± 1.06
Satisfaction with education about the use of RC device prior to discharge home after surgery (scale 1-4)	3.33 ± 0.87	3.59 ± 0.79	3.5 ± 0.81
Likelihood of choosing RC DBS device again (scale 1-5)	3.67 ± 0.94	4.41 ± 1.73	4.15 ± 1.29

- Average charge: every 3.84 days (± 2.62 days) for 1.62 ± 1.18 hours per charging session
- Patients were more satisfied with RC placed as the initial IPG than as conversion (0.51points, p=0.64)
- Patients converted to RC were more satisfied with RC than their non-RC device by 2.01 points (p=0.03)
- Patients converted to RC were more satisfied with size of RC than of non-RC IPGs by 0.7 points (p=0.09)
- Patients did not perceive a difference in symptom control after conversion to RC
- Patients converted to RC were more likely to choose it again than those with initial RC (p=0.26)
- There was little or no correlation between satisfaction with RC device and satisfaction with patient education and counseling prior to discharge after RC implant (Pearson correlation coefficient 0.05).
- 7 patients reported that it was inconvenient to use the manufacturer-provided charging harness but still found it easy to recharge battery at home.

Table 3. Stimulation parameter adjustment after conversion to rechargeable IPG



	amp Δ, all sites	amp Δ, GPi	amp Δ, STN+VIM	PW Δ, all sites	PW Δ, GPi	PW Δ, STN+VIM	freq Δ, all sites	freq Δ, GPi	freq Δ, STN+VIM
average RC (3) / last pre-RC	-5.52%	-3.41%	-10.98%	-4.35%	-3.33%	-7.41%	-9.02%	-10.65%	-3.65%
1st RC / last pre-RC	-9.17%	-8.01%	-12.65%	-2.89%	-1.39%	-7.41%	-9.87%	-11.85%	-3.95%

- First RC vs last non-RC settings – all parameters reduced, more for STN+VIM (amplitude and PW).
- After 3 RC re-programming – all settings remain lower than last non-RC, but amplitude drifts back to baseline, more in GPI.
- All results non-significant (p-value >0.05)

DISCUSSION

- Previous studies on patient satisfaction and stimulation adjustment after battery replacement with another non-RC IPG:
  - Allert 2009 (42 patients with various movements disorders) - 11% of patients had reduced symptom control after post-replacement parameters were decreased in the OR. Returning to the previous settings improved symptoms back to baseline.
  - Blahak 2010 (18 patients with GPI and VIM DBS for dystonia using Soletra IPGs) - stimulation intensity can be reduced by 24.8% after IPG replacement with another non-RC device (authors' hypothesis - gradual decrease in the electrical energy delivered by the IPG in the course of the battery lifetime or neuroplasticity around the time of battery replacement).
  - Harries 2011 (4 dystonia patients converted from non-RC to Activa RC) – 89% would recommend RC but 78% had problems charging battery at home using equipment provided by Medtronic.

- **PATIENT SATISFACTION:**
  - Our study demonstrated high overall satisfaction with RC, slightly higher in patients with initial RC than in subjects converted to RC; it did not correlate with degree of patient education and counseling prior to discharge after RC implant
  - In patients converted to RC, overall satisfaction with initial RC was higher than in converted group (p=0.03).
  - Subjectively, symptom control was no different after conversion to RC

- **PARAMETER ADJUSTMENT AFTER CONVERSION:**
  - Our practice is to generally reduce amplitude by about 10% in the OR at the time of IPG exchange to another non-RC or RC (not in all cases) due to greater efficiency of a new battery and concerns over tolerability.
  - A mild decrease in stimulation parameters after conversion of non-RC to RC IPG might be permitted regardless of the diagnosis or stimulation site (NS). However, initial post-conversion DBS settings (especially amp) tend to drift back towards the last non-RC parameters after a few post-conversion programming sessions.
  - Amplitude drift back to baseline, observed more in GPi DBS, is likely due to high pre-conversion amplitude in patients with TS and dystonia who could not tolerate lower settings after conversion
  - Further reduction of PW after conversion might be explained by the fact that Activa DBS devices allow smaller incremental changes in PW than Soletra stimulators.
  - Frequency remained largely unchanged, likely related to converting 2 single-channel IPGs (Soletra) to one dual-channel RC IPG.

- **CONCLUSIONS:**
- Study limitations – small size and retrospective chart analysis
- Patients are generally very satisfied with RC IPGs but are more satisfied when it is placed as the initial device. After conversion, patients prefer RC IPGs to their prior non-RC IPGs. Practitioners should consider this when advising patients about IPG choices. Recharging equipment may pose inconvenience to some patients.
- Larger prospective studies are needed to establish more definitive guidelines for reprogramming RC after conversion from non-RC IPG.

REFERENCES

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