Degenerative Neurological and Neuromuscular Disease

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CORRIGENDUM

Critical appraisal of rotigotine transdermal system in management of Parkinson's disease and restless legs syndrome – patient considerations [Corrigendum]

Kesayan T, Shaw JD, Jones TM, Staffetti JS, Zesiewicz TA. Degenerative Neurological and Neuromuscular Disease 2015;5:63–72.

The authors would like to correct the following errors: on page 64; paragraph 1, "RTG doses for treatment of early-stage PD monotherapy range from 2 mg/24 hours to 6 mg/24 hours, with recommended titration of 2 mg/24 hours weekly.[5] For adjunct therapy in advanced-stage PD, RTG may be started at 4 mg/24 hour period and titrated up weekly by an additional 2 mg/24 hour period, with a maximum recommended dose of 16 mg/24 hours.[7]" should be "RTG doses for treatment of early-stage PD monotherapy range from 2 mg/24 hours to 8 mg/24 hours (2–6 mg/24 hours in the US), with recommended titration of 2 mg/24 hours weekly.[5] For adjunct therapy in advanced-stage PD, RTG may be started at 4 mg/24 hour period and titrated up weekly by an additional 2 mg/24 hour period, with a maximum recommended dose of 16 mg/24 hours (4–8 mg/24 hours in the US).[5]"

On page 64; paragraph 5, "The mean RTG dose was 8 mg/24 hours, while the mean ropinirole dose was 14.1 mg/day." should have been "The majority of patients (92%) received RTG maintenance dose of 8 mg/24 h, while the median ropinirole dose was 14.1 mg/day."

On page 64; paragraph 6, "Three hundred and forty-one patients were randomized to receive RTG 8 mg/24 hours, 12 mg/24 hours, or placebo for 28 weeks." should have been "Three hundred and forty-one patients were randomized to receive RTG up to 8 mg/24 hours, up to 12 mg/24 hours, or placebo for 28 weeks."

On page 65; Table 1, data in the Doses column and the Notes section have been updated.

Table 1 Efficacy of RTG in early and advanced PD

	Dose (mg/24 hour)	n	Change from baseline ± SD (*P*-value)	
			UPDRS II ADL	UPDRS III motor
Early PD				
Güldenpfennig et al[20]	8 mg/24 hour[a]	25	−2.84±3.45 (0.0004)	−4.88±5.56 (0.0002)
	<8 mg/24 hour[a]	4	−2.25±2.36 (0.1622)	−3.00±3.56 (0.1671)
	Plo	0	–	–
Jankovic et al[21]	5.7 mg/24 hour[b]	177	−0.39 ±0.26 (0.002)	−3.58±0.54 (0.001)
	Plo	96	0.92±0.35 (0.002)	0.38±0.73 (0.001)
Parkinson Study Group[22]	2 mg/24 hour[a]	49	−0.04 (0.94)	−0.90 (0.44)
	4 mg/24 hour[a]	47	−0.84 (0.11)	−1.88 (0.11)
	6 mg/24 hour[a]	48	−0.92 (0.08)	−3.91 (0.001)
	8 mg/24 hour[a]	51	−1.56 (0.003)	−3.82 (0.001)
	Plo	47	–	–
Watts et al[23]	5.7 mg[b]	180	−0.30±3.54	−3.50±7.26
	Plo	96	–	–
Giladi et al[2]	8 mg[c]	215	−2.1[d]	−5.2[d]
	Plo	118	−0.1	−2.1
Trenkwalder et al[25]	2–16 mg	178	−2.6±3.6	−7.0 (0.002)
	Plo	89	−1.3±3.4	−3.9
Advanced PD				
LeWitt et al[26]	≤8 mg/24 h	113	−3.1 (0.004)	−6.8 (0.0185)
	≤12 mg/24 h	109	−3.2 (0.0023)	−8.7 (0.0006)
	Plo	119	−0.5	−3.4

(*Continued*)

Table 1 (*Continued*)

	Dose (mg/24 hour)	n	Change from baseline ± SD (*P*-value)	
			UPDRS II ADL	**UPDRS III motor**
Poewe et al[27]	4–16 mg/24 hour	201	–4.2±4.5 (<0.0001)	–8.7±8.0 (<0.0001)
	Plo	100	–2.0±4.3 (<0.0001)	–4.3±9.3 (<0.0001)

Notes: [a]RTG content per system (mg) originally reported; RTG nominal doses (mg/24 h) were calculated using a ratio of 2.25 (as per US prescribing information[5]), ie, 4.5 mg is equivalent to 2 mg/24 h, 9 mg to 4 mg/24 h, 13.5 mg to 6 mg/24 h, and 18 mg to 8 mg/24 h; [b]The mean (SD) dose was 5.7 (0.84) mg/24 h; 6 mg dose for majority of participants; [c]Ninety-two percent of those in the RTG group were treated with this dose in the maintenance phase and 8% had lower doses; there was no SD reported for UPDRS II or III separately; however, the combined UPDRS part III + part II scores were significantly more improved compared to placebo at the end of the maintenance phase ($P<0.0001$); [d]there was no SD reported for UPDRS II or III separately, however the combined UPDRS part III + part II scores were significantly more improved compared to placebo at the end of the maintenance phase ($P<0.0001$).
Abbreviations: RTG, rotigotine; PD, Parkinson's disease; UPDRS II, Unified Parkinson's Disease Rating Scale part II (activities of daily living); UPDRS III, Unified Parkinson's. Disease Rating Scale part III (motor examination); Plo, placebo.

Table 3 Efficacy of RTG in RLS – change from baseline ± SD (*P*-value)

Study, dose (mg/24 hour)	n	IRLS total score ± SD (*P*-value)	CGI-1 score ± SD (*P*-value)	PSQI total score ± SD (*P*-value)
Inoue et al[40]				
2 mg	95	–14.3±8.9 (0.030)	–	–3.1±3.2 (0.188)
3 mg	94	–14.6±9.0 (0.016)	–	–3.2±3.3 (0.112)
Plo	95	–11.6±8.2	–	–2.5±2.4
Oertel et al[24]				
2 mg[a]	41	–16.5±9.3	–2.7±1.4	–
Plo	20	–9.9±9.9	–1.7±1.5	–
Hening et al[10]				
0.5 mg	98	–10.9±8.9 (0.0682)	4.7±0.8 (0.0603)	–
1 mg	99	–11.1±9.3 (0.0535)	4.6±0.7 (0.0857)	–
2 mg	95	–13.4±9.2 (0.0002)	4.7±0.8 (0.0007)	–
3 mg	103	–14.3±9.4 (<0.0001)	4.7±0.8 (<0.0001)	–
Plo	99	–9.0±7.7	4.7±0.6	–
Trenkwalder et al[8]				
1 mg	148	–14.0±0.8 (<0.0001)	–2.13±0.12 (<0.0001)	–
2 mg	96	–16.4±1.0 (<0.0001)	–2.41±0.14 (<0.0001)	–
3 mg	92	–16.8±1.1 (<0.0001)	–2.55±0.17 (<0.0001)	–
Plo	111	–8.7±0.9	–1.37±0.15	–
Oertel et al[9]				
0.5 mg	50	–10.5±9.2 (0.2338)	–1.6±1.4	–
1 mg	64	–15.3±10.0 (0.0004)	–2.2±1.5 (<0.05)	–
2 mg	49	–15.7±9.5 (0.0003)	–2.4±1.3 (<0.05)	–
3 mg	64	–17.3±10.5 (<0.0001)	–2.7±1.6 (<0.05)	–
4 mg	53	–14.9±10.3 (0.0013)	–2.3±1.5 (<0.05)	–
Plo	53	–9.3±9.6	–1.5±1.4	–
Stiasny-Kolster[41]				
0.5 mg/24 hour[b]	19	–10.5±2.0	–	–
1 mg/24 hour[b]	13	–12.3±2.3	–	–
2 mg/24 hour[b]	17	–15.7±1.9	–	–
Plo	14	–8.0±2.2	–	–

Notes: [a]A mean dose of RTG in the treatment group was reported as 2.1 mg/24 hours; [b]RTG content per system (mg) originally reported; RTG nominal doses (mg/24 h) were calculated using a ratio of 2.25 (as per US prescribing information[5]), ie, 1.125 mg is equivalent to 0.5 mg/24 h, 2.25 mg to 1 mg/24 h, and 4.5 mg to 2 mg/24 h.
Abbreviations: RTG, rotigotine; RLS, restless legs syndrome; SD, standard deviation; IRLS, International Restless Legs Syndrome Study Group severity rating scale; CGI-1, Clinical Global Impressions item-1; PSQI, Pittsburgh Sleep Quality Index; Plo, placebo.

On page 66; paragraph 2, "In an open-label study, advanced-PD patients were treated with levodopa, pramipexole (<1.5 mg/day), or ropinirole (<6.0 mg/day), and RTG (<8 mg/24 hours) for an 8-week treatment period.[7]" should have been "In an open-label study, advanced-PD patients were treated with levodopa, pramipexole (≤1.5 mg/day), or ropinirole (≤6.0 mg/day), and RTG (≤8 mg/24 hours) for an 8-week treatment period.[7]"

On page 68; Table 3, data in the Study, doses column for the Stiasny-Kolster study and the Notes section have been updated.

On page 69; Table 4, the data for the Stiasny–Kolster study and the Notes section have been updated.

Table 4 Side effects present in participants (%) during randomized, double–blinded, placebo–controlled trials

Side effect	Dose (mg/24 hour)	Inoue et al[40]		Hening et al[10]		Trenkwalder et al[8]		Oertel et al[9]		Oertel et al[24,a]		Stiasny–Kolster[41,b]	
		RTG	Plo	RTG	Plo	RTG	Plo	RTG	Plo	RTG	Plo	RTG	Plo
Application site reaction	0.5 mg	–	7.4	22.2	5.0	–	–	9.8	1.8	–	4.8	17.6	28.6
	1 mg	–	–	17	–	35.0	2.0	15.6	–	–	–	38.5	–
	2 mg	42.1	–	34.3	–	41.0	–	16.3	–	17.4	–	26.3	–
	3 mg	50.0	–	34	–	52.0	–	20	–	–	–	–	–
	4 mg	–	–	–	–	–	–	25	–	–	–	–	–
Headache	0.5 mg	–	0	14.1	8.0	–	–	11.8	7.3	–	14.3	11.8	7.1
	1 mg	–	–	12	–	10.0	7.0	7.8	–	–	–	38.5	–
	2 mg	5.3	–	10.1	–	13.0	–	2	–	17.4	–	21.1	–
	3 mg	2.1	–	10.4	–	16.0	–	4.6	–	–	–	–	–
	4 mg	–	–	–	–	–	–	12.5	–	–	–	–	–
Nausea	0.5 mg	–	9.5	13.1	10.0	–	–	5.9	9.1	–	4.8	0.0	14.3
	1 mg	–	–	20	–	9.0	–	9.4	–	–	–	7.7	–
	2 mg	33.7	–	18.2	–	21.0	–	6.1	–	21.7	–	5.3	–
	3 mg	43.6	–	20.8	–	18.0	–	24.6	–	–	–	–	–
	4 mg	–	–	–	–	–	–	23.2	–	–	–	–	–
Fatigue	0.5 mg	–	–	10.1	4.0	–	–	3.9	9.1	–	9.5	0.0	0.0
	1 mg	–	–	3	–	7.0	9.0	4.7	–	–	–	0.0	–
	2 mg	–	–	7.1	–	15.0	–	6.1	–	8.7	–	10.5	–
	3 mg	–	–	6.6	–	11.0	–	10.8	–	–	–	–	–
	4 mg	–	–	–	–	–	–	7.1	–	–	–	–	–
Pruritus	0.5 mg	–	–	9.1	2.0	–	–	5.9	1.8	–	–	5.9	7.1
	1 mg	–	–	2	–	–	–	3.1	–	–	–	15.4	–
	2 mg	–	–	3	–	–	–	0	–	–	–	0.0	–
	3 mg	–	–	7.5	–	–	–	10.8	–	–	–	–	–
	4 mg	–	–	–	–	–	–	3.6	–	–	–	–	–
Hyperhidrosis	0.5 mg	–	–	–	–	–	–	–	–	–	–	–	0.0
	1 mg	–	–	–	–	5.0	3.0	–	–	–	–	0.0	–
	2 mg	–	–	–	–	6.0	–	–	–	–	–	0.0	–
	3 mg	–	–	–	–	4.0	–	–	–	–	–	10.5	–
	4 mg	–	–	–	–	–	–	–	–	–	–	–	–
Somnolence	0.5 mg	–	2.1	8.1	6.0	–	–	–	–	–	9.5	–	–
	1 mg	–	–	10.0	–	–	–	–	–	–	–	–	–
	2 mg	10.5	–	13.1	–	–	–	–	–	10.9	–	–	–
	3 mg	–	–	15.1	–	–	–	–	–	–	–	–	–
	4 mg	–	–	–	–	–	–	–	–	–	–	–	–

Notes: [a]The study did not report the association of adverse events (AE) in relation to the dose of RTG. A mean dose of RTG in the treatment group was reported as 2.1 mg/24 hours; [b]RTG content per system (mg) originally reported; RTG nominal doses (mg/24 h) were calculated using a ratio of 2.25 (as per US prescribing information[5]), ie, 1.125 mg is equivalent to 0.5 mg/24 h, 2.25 mg to 1 mg/24 h, and 4.5 mg to 2 mg/24 h.
Abbreviations: RTG, rotigotine; Plo, placebo.