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Supplementary Material

Article Title: Real-World Outcomes of Paliperidone Palmitate Compared to Daily Oral Antipsychotic Therapy in Schizophrenia: A Randomized, Open-Label, Review Board–Blinded 15-Month Study

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eTable 1. Concomitant Use of Psychotropic Medications (ITT population)

Psychotropic medication, No. (%)	Paliperidone Palmitate (n = 226)	Oral Antipsychotics (n = 218)
Any	168 (74.3)	175 (80.3)
Atypical antipsychotics	100 (44.2)	111 (50.9)
Antidepressants	84 (37.2)	90 (41.3)
Benzodiazepines	45 (19.9)	49 (22.5)
Antihistamines	45 (19.9)	55 (25.2)
Antiextrapyramidal symptoms	52 (23.0)	42 (19.3)
Mood stabilizers and antiepileptics	39 (17.3)	37 (17.0)
Nonbenzodiazepine hypnotics and anxiolytics	33 (14.6)	23 (10.6)
Beta blockers	33 (14.6)	27 (12.4)
Typical antipsychotics	25 (11.1)	28 (12.8)
Depot antipsychotics	4 (1.8)	9 (4.1)
Stimulants	4 (1.8)	0

Abbreviation: ITT = intent-to-treat.

eTable 2. Dose and Exposure of Paliperidone Palmitate and Oral Antipsychotics

	Paliperidone Palmitate	Oral Antipsychotics						
		Aripiprazole	Haloperidol	Olanzapine	Paliperidone	Perphenazine	Quetiapine	Risperidone
Dose per injection records, mg, mean (SD)	n = 226 181.3 (34.2)	NA	NA	NA	NA	NA	NA	NA
Dose per prescription records, mg, mean (SD)	NA	n = 33 15.3 (5.9)	n = 15 8.2 (5.3)	n = 36 13.3 (6.4)	n = 48 6.6 (2.4)	n = 20 16.5 (8.8)	n = 29 339.9 (180.4)	n = 37 3.6 (1.6)
Dose per refill records, mg, mean (SD)	NA	n = 25 16.6 (6.6)	n = 11 7.7 (5.4)	n = 31 13.2 (6.5)	n = 43 6.4 (2.5)	n = 18 14.4 (7.5)	n = 24 335.9 (177.4)	n = 30 3.4 (1.5)
Duration of exposure (days) ^a	n = 226	n = 33	n = 15	n = 36	n = 48	n = 20	n = 29	n = 37
Mean (SD)	266.2 (174.5)	239.1 (176.7)	173.5 (160.8)	281.3 (183.6)	272.8 (185.3)	266.8 (168.8)	280.8 (167.8)	324.2 (178.1)
Median (range)	251.5 (30-479)	242.0 (9-492)	137.0 (11-474)	325.0 (22-496)	315.5 (11-506)	270.0 (31-496)	304.0 (8-511)	427.0 (12-491)
Duration category, n (%)								
≤30	18 (8.0)	2 (6.1)	4 (26.7)	4 (11.1)	4 (8.3)	0 (0)	1 (3.4)	1 (2.7)
31-90	37 (16.4)	9 (27.3)	2 (13.3)	5 (13.9)	9 (18.8)	5 (25.0)	3 (10.3)	8 (21.6)
91-180	36 (15.9)	4 (12.1)	2 (13.3)	4 (11.1)	6 (12.5)	1 (5.0)	7 (24.1)	1 (2.7)
181-270	26 (11.5)	2 (6.1)	2 (13.3)	4 (11.1)	4 (8.3)	5 (25.0)	2 (6.9)	3 (8.1)
271-360	9 (4.0)	5 (15.2)	3 (20.0)	1 (2.8)	3 (6.3)	2 (10.0)	4 (13.8)	2 (5.4)
361-450	41 (18.1)	4 (12.1)	1 (6.7)	5 (13.9)	7 (14.6)	3 (15.0)	4 (13.8)	6 (16.2)
>450	59 (26.1)	7 (21.2)	1 (6.7)	13 (36.1)	15 (31.3)	4 (20.0)	8 (27.6)	16 (43.2)

^aBased on number of injections for the paliperidone palmitate group and number of prescriptions for the oral antipsychotic groups.

eTable 3. Treatment-Emergent Adverse Events (TEAEs) Leading to Study Drug Discontinuation^{a,b}

TEAE-Related Study Discontinuation, No. (%)	Paliperidone Palmitate (n = 226)	Oral Antipsychotics (n = 218)
Any	27 (11.9)	17 (7.8)
Body system/Preferred term ^c		
Psychiatric disorders	9 (4.0)	10 (4.6)
Depressive symptom	2 (0.9)	0
Psychotic disorder	2 (0.9)	0
Schizophrenia	1 (0.4)	5 (2.3)
Anxiety	1 (0.4)	2 (0.9)
Insomnia	1 (0.4)	0
Agitation	1 (0.4)	0
Abnormal dreams	1 (0.4)	0
Libido decreased	1 (0.4)	0
Substance abuse	1 (0.4)	0
Suicidal ideation	1 (0.4)	0
Paranoid schizophrenia	1 (0.4)	0
Depression	0	2 (0.9)
Auditory hallucination	0	2 (0.9)
Disorganized schizophrenia	0	1 (0.5)
Suicide attempt	0	1 (0.5)
Nervous system disorders	8 (3.5)	8 (3.7)
Akathisia	2 (0.9)	2 (0.9)
Headache	2 (0.9)	0
Dystonia	1 (0.4)	3 (1.4)
Dizziness	1 (0.4)	1 (0.5)
Tardive dyskinesia	1 (0.4)	1 (0.5)
Dyskinesia	1 (0.4)	0
Oromandibular dystonia	1 (0.4)	1 (0.5)
Extrapyramidal disorder	1 (0.4)	0
Parkinsonism	0	2 (0.9)
Reproductive system and breast disorders	6 (2.7)	0
Erectile dysfunction	2 (0.9)	0
Amenorrhea	1 (0.4)	0
Ejaculation failure	1 (0.4)	0
Galactorrhea	1 (0.4)	0
Gynecomastia	1 (0.4)	0
General disorders and administration site conditions	4 (1.8)	0
Injection site pain	2 (0.9)	0
Chest discomfort	1 (0.4)	0
Sudden death	1 (0.4)	0
Investigations	3 (1.3)	0
Weight increased	2 (0.9)	0
Semen volume decreased	1 (0.4)	0

^aThis table comprised data from randomization until the end of randomly assigned treatment (28 days after the last injection of paliperidone palmitate or 1 day after the last dose of oral antipsychotic).

^bDefined as adverse events with an incidence of ≥ 1 by body group in either treatment group.

^cPreferred terms of adverse events were based on version 12.0 of the Medical Dictionary for Regulatory Activities (MedDRA; Medical Dictionary for Regulatory Activities (MedDRA). Version 12.0. <http://www.meddra.org>. Accessed March 13, 2015).

eTable 4. Treatment-Emergent Prolactin-Related Adverse Events by Preferred Term^a for Male and Female Subjects^b

	Paliperidone Palmitate	Oral Antipsychotics
Male subjects, no. (%)	(n = 193)	(n = 190)
Any	42 (21.8)	7 (3.7)
Erectile dysfunction	17 (8.8)	0
Decreased libido	13 (6.7)	3 (1.6)
Increased blood prolactin	7 (3.6)	1 (0.5)
Breast tenderness	2 (1.0)	1 (0.5)
Gynecomastia	3 (1.6)	0
Breast pain	1 (0.5)	0
Sexual dysfunction	1 (0.5)	0
Hyperprolactinemia	4 (2.1)	2 (1.1)
Anorgasmia	3 (1.6)	0
Loss of libido	1 (0.5)	0
Females, no. (%)	(n = 33)	(n = 28)
Any	11 (33.3)	2 (7.1)
Amenorrhea	5 (15.2)	1 (3.6)
Galactorrhea	5 (15.2)	0
Irregular menstruation	2 (6.1)	1 (3.6)
Hyperprolactinemia	2 (6.1)	1 (3.6)
Increased blood prolactin	2 (6.1)	0

^aPreferred terms of adverse events were based on version 12.0 of the Medical Dictionary for Regulatory Activities (MedDRA; Medical Dictionary for Regulatory Activities [MedDRA]. Version 12.0. <http://www.meddra.org>. Accessed March 13, 2015).

^bThis table comprised data from randomization until the end of randomly assigned treatment (28 days after the last injection of paliperidone palmitate or 1 day after the last dose of oral antipsychotic).