

## 리스페리돈 장기 지속형 주사제의 효용과 안정성 : 12주 다기관 경구 항정신병약물로부터 교체연구

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이상열<sup>7</sup> · 이양현<sup>8</sup> · 홍경수<sup>9</sup> · 김대호<sup>10</sup> · 김영훈<sup>11</sup> · 김창윤<sup>1</sup>

1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 가

### ABSTRACT

#### Effectiveness and Tolerability of Long-Acting Risperidone : A 12 Weeks, Multi-center Switching Study from Oral Antipsychotics

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**Objective :** To evaluate maintained effectiveness and tolerability when treated with long-acting risperidone compared to the previous antipsychotics in patients with schizophrenia or other psychotic disorders and to compare maintained effectiveness between oral risperidone and non-risperidone subgroups.

**Methods :** Subjects aged at least 18 years who required long-term antipsychotic therapy and who have been symptomatically stable on a stable dose of antipsychotics during the last month were enrolled in the non-rando-

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1  
1  
1)  
2) 3) clozapine  
(esterification) , 가  
4)  
(glycolic acid) - (lactate) 5)  
(microsphere) 6)  
가 7) 8) 30  
가  
9) 2 가 9)  
2~3  
12 7 2 6  
가 , 25 mg  
가  
10) 1  
가  
, 2-4  
가  
, 2 2  
, 3  
11-14)

**대상 및 방법**

12  
20  
1) 18  
2) IV  
DSM -  
3)

**1. 효능성/안정성 평가**

가 (1 ), 4 (2 ), 8  
(3 ) 12 (4 / )  
가 (PANSS),  
Clinical Global Impression(CGI), Global Assessment  
of Functioning(GAF) 가 ,  
55 가(ESRS),  
가 . 가  
가  
, PANSS

CGI 가 . PANSS 가 . PANSS  
 PANSS 20% , PANSS  
 4가 (delusion, conceptual disor- (between group  
 ganization, hallucinatory behavior, suspiciousness/per- effect)  
 secution) 2 가 analysis of variance)  
 4 (moderate) , 가 <sup>2</sup> test (repeated measures  
 , CGI 가  
 CGI 2  
 , CGI 가 4  
 , 3  
 가 2 가  
 1 . CGI 가  
 204 ( 101 , 103  
 27.2 , 8.2±6.7  
 , 2.4 가  
 192 가 ,  
 PANSS  
 59.1 , CGI 3.3  
 (mild to moderate)  
 60 CGI 가 3 (mild)  
 , PANSS 4 (mo-  
 derate)  
 “ ” “  
 ” 5  
 가 . , , PANSS  
 , CGI 가 ( 1).  
 가가  
 가 ,  
 가  
 가 . 가 22.5% .  
 가 14 가 ,  
 11 . 6  
 ( 2), 가 1  
 ,  
 .

**결 과**

**1. 인구학적 특성**

1 204 ( 101 , 103  
 / : 192/12)가  
 204 35.6±9.9  
 27.2 , 8.2±6.7  
 , 2.4 가  
 192 가 ,  
 PANSS  
 59.1 , CGI 3.3  
 (mild to moderate)

**2. 통계분석**

가 , , PANSS  
 , CGI 가 ( 1).  
 가가  
 가 ,  
 가  
 가 . 가 22.5% .  
 가 14 가 ,  
 11 . 6  
 ( 2), 가 1  
 ,  
 .

32 (69.6%) 가  
 , 9 (19.6%), 3 (6.5%)  
 .

3. 리스페리돈 장기 지속형 주사제 및 기존 경구용 항정  
 신병약물의 종류와 용량  
 25 mg

**Table 1.** Baseline demographic and clinical characteristics

	Risperidone group (N=139)	Non-risperidone group (N=65)	Total group (N=204)
Age (yrs)	35.3 ± 10.2	36.3 ± 9.4	35.6 ± 9.9
Sex (M/F)	70/69	31/34	101/103
Duration of illness (yrs)	8.6 ± 7.4	7.3 ± 4.7	8.2 ± 6.7
Age at onset	26.5 ± 9.2	28.6 ± 9.8	27.2 ± 9.4
Number of hospitalization	2.1 ± 1.7	2.7 ± 2.7	2.4 ± 2.2
Diagnosis			
Schizophrenia	131 (94.2%)	61 (93.8%)	192 (94.1%)
Paranoid	92 (70.2%)	43 (70.5%)	135 (70.3%)
Undifferentiated	20 (15.3%)	7 (11.5%)	27 (14.1%)
Disorganized	5 ( 3.8%)	1 ( 1.6%)	6 ( 3.1%)
Residual	13 ( 9.9%)	10 (16.4%)	23 (12.0%)
Catatonic	1 ( 0.8%)	0 ( 0%)	1 ( 0.6%)
Schizophreniform disorder	2 ( 1.4%)	0 ( 0%)	2 ( 1.0%)
Schizoaffective disorder	3 ( 2.2%)	1 ( 1.5%)	4 ( 2.0%)
Other psychosis	3 ( 2.2%)	3 ( 4.7%)	6 ( 2.9%)
Baseline PANSS score			
Total score	58.2 ± 17.2	61.0 ± 18.2	59.1 ± 17.6
Positive subscale	13.2 ± 4.9	13.5 ± 4.7	13.3 ± 4.9
Negative subscale	13.4 ± 5.3	16.0 ± 6.1	15.6 ± 5.6
General subscale	29.6 ± 9.1	31.5 ± 9.5	30.2 ± 9.3
Baseline CGI	3.2 ± 1.0	3.4 ± 1.1	3.3 ± 1.0

PANSS : Positive and Negative Syndrome Scale, CGI : Clinical Global Impressions

**Table 2.** Cumulative frequency and reasons for drop outs

	Baseline	4 weeks	8 weeks	12 weeks
Number of subjects	204	194	171	158
Cumulative frequency of drop outs (%)		10 (4.9%)	33 (16.2%)	46 (22.5%)
Reasons for drop outs				
Insufficient response				11 (23.9%)
Adverse event				6 (13%)
Subject non-compliant for other reasons				3 ( 6.5%)
Protocol violation				3 ( 6.5%)
Subject withdrawal consent				6 (13%)
Subject lost to follow-up				14 (30.4%)
Death				1 ( 2%)
Missing data				2 ( 4.3%)

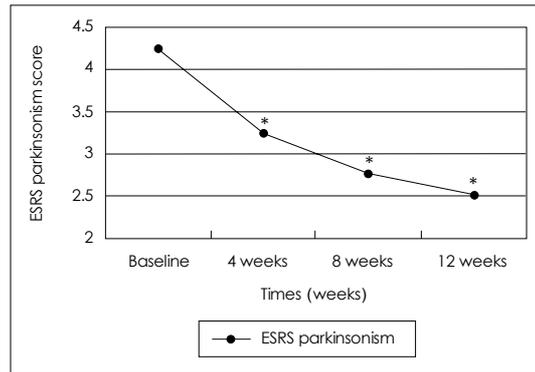


**Table 4.** Mean changes from baseline to endpoint in PANSS score†

PANSS score	Risperidone group§ (N=139)	Non-risperidone group (N=65)	Total (N=204)
Total score			
Baseline	58.2 ± 17.2	61.0 ± 18.2	59.1 ± 17.6
Endpoint	50.8 ± 19.0*	50.1 ± 15.5*	50.6 ± 17.9*
Positive subscale			
Baseline	13.2 ± 4.9	13.5 ± 4.7	13.3 ± 4.9
Endpoint	11.6 ± 5.4*	11.1 ± 4.1*	11.5 ± 5.0*
Negative subscale			
Baseline	15.4 ± 5.3	16 ± 6.1	15.6 ± 5.6
Endpoint	12.9 ± 5.3*	13.0 ± 5.1*	12.9 ± 5.2*
General subscale			
Baseline	29.6 ± 9.1	31.5 ± 9.5	30.2 ± 9.3
Endpoint	26.2 ± 9.7*	26.0 ± 7.7*	26.2 ± 9.3*

\* : p < 0.01 vs. baseline. † : paired T-test, ‡ : LOCF analysis was performed, § : Risperidone vs. Non-risperidone : statistically not significant. repeated measures ANOVA

3, 1  
139, 8.0%가  
39, 7.7%  
85  
4 (4.7%)  
CGI  
CGI  
3.3, 2.8  
(mild to moderate)  
(very mild to mild) 3)  
CGI  
59, 28.9%  
11 (5.4%)  
GAF  
57.8 ± 11.6, 가  
62.8 ± 12.9, 67.2% 가  
(27.5%) (20.6%) (



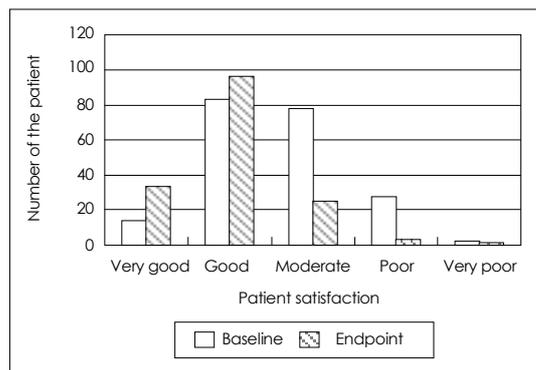
**Figure 3.** Mean change from baseline to endpoint in ERS parkinsonism score. \* : p < 0.01 vs. baseline.

### 5. 안정성 및 환자의 만족도

가  
, 가  
(

**Table 5.** Frequency of treatment-emergent adverse events (%)

Events	Total (N=204)	Risperidone (N=139)	Prior oral antipsychotics	
			Non-risperidone (N=65)	
			Olanzapine (N=39)	Non-olanzapine (N=26)
Any adverse events	137 (67.2)	96 (69.1)	26 (66.7)	15 (57.7)
Extrapyramidal symptoms	56 (27.5)	42 (30.2)	11 (28.2)	3 (11.5)
Tardive dyskinesia	3 ( 1.5)	2 ( 1.4)	0 ( 0)	1 ( 3.8)
Akathisia	25 (12.3)	16 (11.5)	6 (18.0)	3 (11.5)
Insomnia	42 (20.6)	32 (23.0)	4 (15.4)	6 (23.1)
Anxiety	25 (12.3)	20 (14.4)	2 ( 5.1)	3 (11.5)
Anticholinergic adverse event	15 ( 7.4)	11 ( 7.9)	3 ( 7.7)	1 ( 3.8)
GI trouble	13 ( 6.4)	9 ( 6.5)	3 ( 7.7)	1 ( 3.8)
Agitation	10 ( 4.9)	5 ( 3.6)	2 ( 5.1)	3 (11.5)
Sedation	1 ( 0.5)	1 ( 0.7)	0 ( 0)	0 ( 0)
Headache	2 ( 1.0)	2 ( 1.4)	0 ( 0)	0 ( 0)
Elevated hepatic enzyme	1 ( 0.5)	0 ( 0)	1 ( 2.6)	0 ( 0)



**Figure 4.** Patient satisfaction at baseline and endpoint.

5). “ ” “ ”

가 204 97 47.5% , 139 35 (25.3%), 39

“ ” “ ” 6 (15.4%) , 39

152 129 (84.8%) ( 4). 158 43 (27.2%) , 107

**6. 병용약물** 35 (32.7%), 30 4

204 77 (37.7%) (13.3%) , 99 27

, 139 60 (27.3%) , ,

(77.9%), 65 79 21 (26.6%), 32



가 4 , BPRS CGI CGI

4 가 , 3 60%

77% . Lauriello <sup>14)</sup>

PANSS 가 PANSS CGI 3 가 가 15%

20% , PANSS 4가 35% 가 , Lindenmayer

(delusion, conceptual disorganiztion, 12) 61% . 43%

2 , 가 (E-

가 4 (moderate) , SRS) 가 .

가 ,

. PANSS 가

17.9% 13.3%

PANSS 20 가 77.9% 11.2%, 37.7% 19.0%

가 .

가

LOCF 가

LOCF 가 <sup>12,13,20)</sup>

158 , 가

가

6 (3.8%) , 204

가

15 (7.4%) .

PANSS

36.8%, 9% , CGI 가 99 가 27

28.9%, 5.4% PANSS (27.2%) 가

가

PANSS CGI 20.6%, 12.3%

가

25 mg 가 88% ,  
 25 mg 가 54% 37.5  
 mg 42% . 가 가 .  
 mg 25 mg 37.5 **결 론**  
 , 37.5 mg 20  
 (N=192) (N=12)  
 , PANSS 12  
 , GAF 가 가 .  
 가 가 PANSS , ,  
 가 가 . PANSS 20%  
 가 가 . 36.8%가  
 가 2 . 12 204  
 7.4% .  
 , 가 ,  
 9,21) 가 ,  
 가 22) .  
 , 가 가

중심 단어 :

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