

Psychosocial functioning of schizophrenic patients in post-acute treatment with long-acting injectable risperidone in ambulatory care

Juckel G¹; Diekamp B³; Ibach B²; Hargarter L³

¹LWL-Klinik Bochum der Ruhr-Universität Bochum, Germany; ²Psychiatrische Dienste Thurgau, Münsterlingen, Switzerland;

³Medical & Scientific Affairs, Janssen-Cilag GmbH, Neuss, Germany

Introduction

Improvement of social and occupational functioning is a major goal in the treatment of schizophrenic patients and therefore may improve reintegration of patients and their ability to lead an independent life.

This study investigated the safety and efficacy of risperidone long-acting injectable (RLAI) in the post-acute treatment of schizophrenic patients, especially with regard to improving and/or stabilizing the pathology of disease and improving the social and occupational functioning.

Methods

- Interim-analysis (12 months after enrollment of the first 90 patients) of a non-interventional, prospective, single-arm, multi-center study (RISSCH4091) over 52 weeks.
- Patients (m/f, 18-65 years) in the post-acute stage of schizophrenia (transfer to outpatient clinic after treatment of exacerbation or first manifestation of schizophrenia as (partial) in-patient) (ICD-10 F20.x; duration of disease ≤10 years).
- Indication to and start of long-term antipsychotic monotherapy with RLAI; individual treatment and diagnostic procedures were at the discretion of the treating physician.
- Documentation of treatment at baseline and at week 2, 4, 12, 24, 36 and 52.
- Presented here is the assessment of the treatment based on the Clinical Global Impression (CGI), the Global Assessment of Functioning (GAF), skills assessing the ability of patients for reintegration as quantified by the German short version of the International Classification of Functioning, Disability and Health for Mental Disorders (Mini-ICF-APP; Linden M et al. Verlag Hans Huber, 2009) and adverse events (AEs).

Results

Table 1 Demographic Data

Patients ITT-population (n)	75
Gender, m : f (n (%))	48(64%) : 27(36%)
Mean age ± SD (years)	32.7 ± 9.1
Mean duration of disease ± SD (years)	2.7 ± 3.2
Mean observation period ± SD (years)	278.8 ± 119.3
Diagnosis according to ICD-10 (n; multiple answers possible)	
F 20.0 Paranoid schizophrenia	67(89.3%)
F 20.1 Hebephrenic schizophrenia	1 (1.3%)
F 20.3 Undifferentiated schizophrenia	4 (5.3%)
F 20.4 Post-schizophrenic depression	1 (1.3%)
F 20.5 Residual schizophrenia	2 (2.7%)
Additional axis Ia-disorders	
No additional disorders	37 (49.3%)
F10.1-F19.1 Psychotropic substance use	29 (38.7%)
F10.2-F19.2 Dependence syndrome	5 (6.7%)
Other disorders acc. to ICD-10 chapter V(F)	7 (9.3%)

- Data of 88 patients who had received RLAI were analyzed (safety set). The median starting and end dose of RLAI was 37.5 mg/2 weeks. Efficacy data were available from 75 patients (intent-to-treat (ITT)-population). → Tab. 1
- GAF total scores improved significantly during the course of the study by 24.4±23.7 points versus baseline (p<0.0001). 76.0% of the patients improved significantly in the CGI-C scores from 1.96±0.68 to 1.18±0.94 at final observation. 6.7% of the patients showed a worsening of the CGI-C. → Fig. 1
- Mini-ICF-APP total scores improved from 1.96±0.68 to 1.18±0.94; the differences in all items as well as the total score were significant (p<0.001). → Fig. 2. Some items of the Mini-ICF-APP improved markedly. → Fig. 3
- For the following sub-items more than 50% of the patients improved from baseline to last visit: planning/structuring the day (52%), flexibility (56%), professional competency (53%), endurance (53%), contacts/interactions in public roles (56%), spare-time/ non job-related activities (57%) and self-care (55%). → Fig. 4
- At the final visit 74.7% of the patients had at least one non-occupational activity per week, that is 2.3 activities per week more than at baseline.

Tolerability/Safety

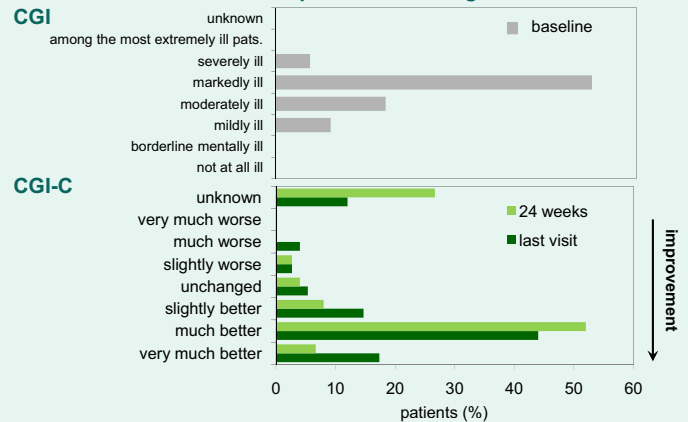
- 119 adverse events (AEs) were reported in 47 (53.4%) patients (safety set).
- 54 AEs (45.4%) were at least possibly related to RLAI, as assessed by the treating physician; the most common AEs (n>2) were drug ineffective 8.0% (7), weight increase 8.0% (7), psychotic disorder 5.7% (5), anxiety 3.4% (3) and EPS 3.4% (3).
- 14 (11.8%) serious AEs in 6 patients were rated at least possibly related to RLAI by the treating physician; most common was psychotic disorder 4.5% (4).

Conclusions

The Mini-ICF-APP is a suitable instrument for the assessment of disorders of functioning, capacity and participation in patients with psychological disorders. Results of this interim analysis indicate that treatment with risperidone long-acting injectable may improve global functioning of patients by reducing typical disorder of functioning, capacity and participation. Treatment with risperidone long-acting injectable may help patients to reintegrate into social and occupational environments.

Results

Fig. 1 CGI – Clinical Global Impression
CGI-C – Clinical Global Impression - Change



Mini-ICF-Rating for Psychological Disorders (Mini-ICF-APP)

Observer-rating instrument to define/measure disorders of activity, capacity and participation, especially in regard to social functioning in a standard environment. The rating reflects the "environment adjusted ability of the individual", "the execution of a task or action by an individual" and whether a person can fulfill role requirements (see World Health Organization (2001) International Classification of Functioning, Disability and Health (ICF). WHO, Geneva; Mini ICF-APP; Linden M et al. Verlag Hans Huber, 2009).

RATING: 0: no impairment 1: mild impairment 2: moderate impairment
3: marked impairment 4: severe/total impairment, i.e. can not fulfill respective requirements at all

Fig. 2 Mean Mini-ICF-APP total scores

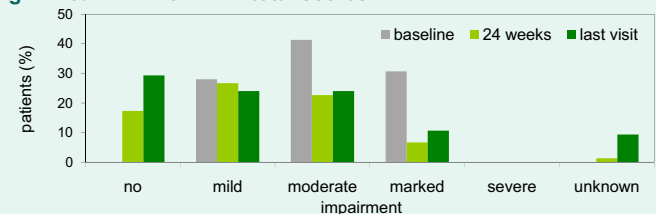


Fig. 3 Mini-ICF-APP sub-items

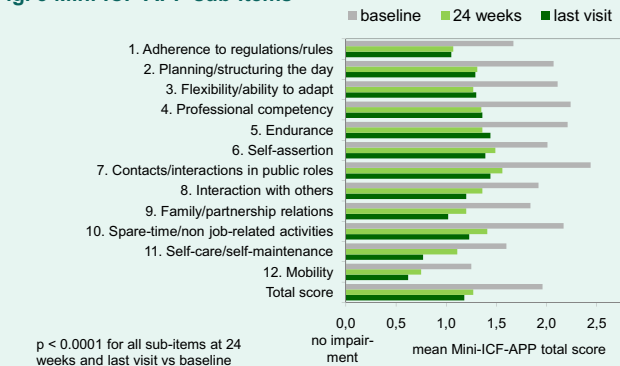


Fig. 4 Distribution of level of impairments in Mini-ICF-APP sub-items

