Psychiatr Q (2016) 87:293–304
DOI 10.1007/s11126-015-9385-z

ORIGINAL RESEARCH

Quality of Life and Hormonal, Biochemical, and Anthropometric Profile Between Olanzapine and Risperidone Users

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Published online: 29 July 2015

Abstract This cross-sectional study compared quality of life and side effects in 108 users of olanzapine or risperidone suffering schizophrenia and being attended at psychiatric ambulatory services in Rio Grande do Norte, Brazil. Economic, socio-demographic, anthropometric, biochemical, and hormonal variables were compared. The EuroQoL Five-Dimension Scale (EQ-5D) was used to evaluate quality of life, and side effects were assessed using the Udvalg for Kliniske Undersøgelser (UKU) Side Effect Rating Scale and the Simpson–Angus Scale. Data were analysed using the χ^2 test and Student's t test, with a significance level of 5 %.The household incomes of approximately 80 % of patients were <2.0 minimum wages ($678). Anthropometric variables (waist circumference, hip circumference, weight, waist-to-hip ratio) and systolic and diastolic blood pressure were noted among male olanzapine users (all $p < 0.05$). EQ-5D scores showed that olanzapine use significantly impacted self-help ability ($p < 0.001$). Risperidone users had a mean

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quality-adjusted life year value of 1. Mean total Simpson–Angus Scale scores was 0.38 for olanzapine users and 0.11 for risperidone users ($p < 0.02$). Significant differences in UKU were observed for the following items: asthenia/lassitude/fatigue (higher among olanzapine users, $p = 0.02$), dystonia (higher among olanzapine users, $p = 0.01$), tremors (higher among olanzapine users, $p = 0.03$), gynecomastia (higher among risperidone users, $p < 0.02$), and ejaculatory dysfunction (higher among risperidone users, $p < 0.02$). Olanzapine users had impaired quality of life, which can be explained in part by adverse motor, biochemical, and hormonal effects characteristic of metabolic syndrome.

Keywords Schizophrenia · Olanzapine · Risperidone · Quality of life · Secondary effects

Introduction

The introduction of new antipsychotic drugs has ushered in a new era in the treatment of psychiatric disorders, particularly schizophrenia [1]. Chlorpromazine and haloperidol, considered to be typical antipsychotics, were among the most commonly used drugs. In addition to their therapeutic effect, classic typical antipsychotics can cause side effects like extrapyramidal symptoms, including Parkinsonian syndrome, acute dystonic reactions, akathisia, dyskinesia, and neuroleptic malignant syndrome [2].

Originally, the term "atypical antipsychotic" was used to distinguish clozapine from the many other drugs developed for the treatment of schizophrenia. Clozapine is as effective as other drugs, but has a considerably lower propensity to induce acute and chronic extrapyramidal symptoms. After the introduction of radioactive isotope receptor–binding techniques in the late 1970s, which enabled classification of antipsychotic drugs on the basis of their receptor affinities [3], the term "atypical antipsychotic" was expanded into a heuristic concept.

The introduction of atypical antipsychotics decreases the risk of developing extrapyramidal adverse events during treatment [4, 5]. Olanzapine and risperidone represent an interesting advance in treatment of schizofrenia, but they are no free of secondary effects. Olanzapine has the main adverse effect of metabolic syndrome, which can increase

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the risk of diabetes and cardiovascular diseases [6, 7]. Risperidone has dose-dependent extrapyramidal effects and causes changes in prolactin concentration, which can leads to disturbances in sexual function such as gynecomastia and galactorrhea [8]. However, the adverse effects of these medicines and their ability to achieve real gains in quality of life require investigation.

Research performed by our group found no significant gain in quality of life among users of atypical antipsychotics, which may be explained in part by unfavourable socio-economic conditions [9, 10]. Thus, the aim of the present study was to examine hormonal and biochemical side effects and quality of life in a sample of olanzapine and risperidone users attended at ambulatory care.

Methods

This cross-sectional study was conducted in Natal, RN, Brazil (year 2014). Adult (aged >18 years) patients diagnosed with schizophrenia, according to *International Classification of Diseases* 10 and *Diagnostic and Statistical Manual of Mental Disorders* IV criteria [11], who had been treated with olanzapine or risperidone for ≥1 year were considered for inclusion in the study. Participants and their family members provided written informed consent (protocol no. 001/06-CEP/UERN). The study was conducted in accordance with the Declaration of Helsinki [12].

Sample Size Calculation

In 2014, 5400 patients of the ambulatory services of João Machado Hospital received atypical antipsychotic drugs (olanzapine, 44 %; risperidone, 33 %; other antipsychotics, 23 %). To calculate the appropriate sample size, we used a 95 % confidence interval and a 15 % tolerable sampling error. Considering the finite population and the prevalence of risperidone use (among atypical antipsychotics, due to its lower cost), the following formula was used:

$$n = z^2_{\alpha/2} NP(1-P)$$

$$\varepsilon^2(N-1) + z^2_{\alpha/2} P(1-P),$$

where n is the sample size, $z_{\alpha/2}$ is the confidence interval, P is the prevalence, N is the population, and ε is the tolerable sampling error. According to this calculation, the required sample size was 108 patients (65 olanzapine and 43 risperidone users).

Data Collection

All assessments were conducted at baseline, with the exception of quality of life. Economic and socio-demographic variables (age, sex, education, household income, social security) were assessed using a structured questionnaire. Anthropometric variables [waist circumference, height, hip circumference, weight, body mass index (BMI), waist-to-hip ratio], blood pressure, hormone levels (cortisol and prolactin), and biochemical parameters [glucose, triglycerides, total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein cholesterol (LDL), Glutamic oxaloacetic transaminase (STGO),

Glutamic-pyruvic transaminase (SGPT), urea, creatinine, and gamma-glutamyltransferase (γ-GT)] were measured in Pharmacology Laboratory (UFRN, Natal, Brazil).

Reference values for the examination of biochemical and anthropometric variables were obtained from the Adult Treatment Panels III and IV [13] and the Brazilian Guidelines on Dyslipidaemia and Prevention of Atherosclerosis [14]. According to these references, the following values were used to define abnormality: waist circumference ≥94 cm for men and ≥80 cm for women, diastolic blood pressure ≥85 mmHg and/or systolic blood pressure ≥130 mmHg, and total cholesterol >200 mg/dL (dyslipidaemia in cases of total cholesterol <200 mg/dL in association with HDL cholesterol), triglycerides ≥150 mg/dL, and fasting glucose ≥100 mmHg. Analyses of height, hip circumference, weight, BMI, and waist-to-hip ratio were stratified by sex.

Quality of life was assessed by interview at baseline and after 12 months using the EuroQol Five-Dimension Scale (EQ-5D), which has been validated in Brazil [15]. This instrument was used to evaluate the frequency of problems in five dimensions of health (mobility, self-help, habitual activities, pain, and anxiety/depression) on a three-point scale ranging from 1 to 3. Scores were dichotomised as 'no problem' (1) or 'problem(s)' (2, 3). Quality-adjusted life years (QALYs; 1 QALY = 1 year of life in perfect health) were calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighing each year with a quality of life score. QALYs reflect a person's ability to perform activities of daily life and his/her freedom from pain and mental disturbance.

Adverse events related to antipsychotic drug use were assessed using the Udvalg for Kliniske Undersøgelser (UKU) Side Effect Rating Scale [16], which rates symptom severity and the perception or assessment that a symptom is a side effect. The UKU Scale is divided into four sections: psychiatric symptoms (10 items), neurological symptoms (8 items), autonomic symptoms (11 items), and other effects (19 items). The severity of each item is rated on a scale ranging from 0 to 3.

The Simpson–Angus Scale, developed in 1970, was used to assess drug-induced parkinsonism and related extrapyramidal side effects [17]. This scale has demonstrated clinical validity and a high degree of inter-rater reliability. It comprises 10 items measuring rigidity (six items), gait (hypokinesia), glabellar reflex, tremors, and salivation (one item each). Each item is scored on a five-point scale ranging from 0 to 4. The total score is the sum of items divided by 10, with a total score >0.3 indicating the presence of extrapyramidal symptoms [18].

Data Analysis

Socio-economic, socio-demographic, and clinical variables were compared between atypical antipsychotic groups using the χ^2 test and Test t student. EQ-5D, UKU Side Effect Rating Scale, and Simpson–Angus Scale scores were compared using Test t student. A p value <0.05 was considered to be significant.

Results

The demographic characteristics of the study participants are shown in Table 1. Significantly more men than women received olanzapine, whereas more women received risperidone ($p = 0.008$). The household incomes of approximately 80 % of patients were

Table 1 Socio-economic variables of patients suffering schizophrenia being treated with olanzapine or risperidone at baseline

Characteristic	Olanzapine (n = 65)	Risperidone (n = 43)	*p*
Age (years; mean ± standard deviation)	34.4 + 12.5	45.3 + 12.1	0.09
Gender (%)			
Female	30.0	70.0	0.008**
Male	67.7	32.3	
Education (years)			
≤8	49.1	53.7	0.55
>8	50.9	46.3	
Household income[a]			
≤2	81.3	78.2	0.49
>2	18.7	21.8	
Social security			
Yes	35.9	47.3	0.36
No	64.1	52.7	

** Significant difference between groups

[a] Minimum wage In Brazil, March 2015

<2.0 minimum wages ($678), and participants had low educational levels (≤8 years in 50 % of individuals). The majority (52.7–64.1 %) of individuals had received no social security. These socio-economic characteristics did not differ between groups.

Anthropometric and blood pressure values for the study participants are shown in Table 2. Compared with male risperidone users, male olanzapine users had significantly greater mean waist circumference ($p < 0.01$), hip circumference ($p < 0.02$), and weight ($p < 0.02$). The only anthropometric variable that differed between female olanzapine and risperidone users was height ($p < 0.01$). Mean systolic and diastolic blood pressure ($p < 0.04$) and waist-to-hip ratio ($p < 0.01$) were higher in olanzapine than in risperidone users (Table 2).

Hormonal and biochemical values for the study participants are shown in Table 3. Among olanzapine users, significant differences were observed in the levels of triglycerides ($p < 0.04$), HDL cholesterol Male ($p < 0.02$), SGOT ($p < 0.01$), SGPT ($p < 0.01$), γ-GT ($p < 0.03$), and cortisol ($p < 0.01$). Among risperidone users, prolactin differed significantly ($p < 0.04$).

Figure 1 shows the distribution of reported problems in EQ-5D dimensions at baseline and 12 months. Olanzapine use significantly impaired patients' self-help abilities at baseline and 12 months ($p < 0.001$). No significant difference between medications was observed in the other dimensions at baseline or 12 months, but many individuals reported problems. The percentages of individuals in both groups with mobility problems increased over the study period (from 26.2 to 29.2 % among olanzapine users, and from 27.9 to 37.2 % among risperidone users). The percentage of patients in both groups with problems in the habitual activities domain increased from 47.7 to 60 %. An increase in the percentage (from 55.8 to 74.4 %) of risperidone users with anxiety and depression problems was also observed. The mean QALY value was higher for risperidone than for olanzapine users ($p = 0.032$) (Table 4).

Total mean Simpson–Angus Scale scores ($p < 0.02$), as well as scores for gait ($p < 0.01$), wrist rigidity ($p < 0.03$), and tremor ($p < 0.00$), were higher among olanzapine

Table 2 Anthropometric indices and blood pressure of olanzapine (65) and risperidone (43) users

Anthropometric index	Olanzapine	Risperidone	*p*
Waist circumference (cm)			
Female	101.5 ± 13.0	97.8 ± 12.8	0.50
Male	107.1 ± 10.7	95.7 ± 13.1	0.01*
Height (cm)			
Female	161.2 ± 5.0	153.6 ± 5.6	0.01*
Male	173.5 ± 8.3	168.6 ± 8.4	0.14
Hip circumference (cm)			
Female	102.3 ± 7.8	105.4 ± 7.1	0.40
Male	108.8 ± 5.8	101.8 ± 9.1	0.02*
Weight (kg)			
Female	69.4 ± 12.3	66.7 ± 11.6	0.63
Male	87.1 ± 11.8	74.5 ± 16.3	0.02*
Body mass index (kg/m^2)			
Female	26.8 ± 5.3	28.1 ± 4.4	0.56
Male	28.5 ± 4.1	26.7 ± 3.5	0.28
Waist-to-hip ratio	0.99 ± 0.08	0.93 ± 0.07	0.01*
Blood pressure (mmHg)			
Systolic	124.8 ± 16.7	114 ± 18.9	0.04*
Diastolic	83.5 ± 14.6	75.4 ± 13.3	0.04*

Data are presented as means ± standard deviations

* Statistically significative difference between groups

Table 3 Hormonal and biochemical characteristics of olanzapine (65) and risperidone (43) users

Blood parameters	Olanzapine	Risperidone	*p*
Glucose (mg/dL)	84.8 ± 19.5	85.7 ± 25.7	0.88
Triglycerides (mg/dL)	176.4 ± 145.4	109.4 ± 50.4	0.04*
Total cholesterol (mg/dL)	184.1 ± 38.2	177.7 ± 40.9	0.57
HDL cholesterol (mg/dL)			
Female	50.5 ± 22.2	40.7 ± 7.6	0.16
Male	37.0 ± 7.8	44.9 ± 9.5	0.02*
LDL cholesterol (mg/dL)	109.9 ± 31.5	113.8 ± 41.9	0.72
SGOT (U/I)	27.22 ± 12.8	19.2 ± 6.1	0.01*
SGPT TGP (U/I)	37.3 ± 29.6	19.6 ± 10.6	0.01*
Urea (mg/dL)	25.3 ± 6.6	23.3 ± 6.4	0.30
Creatinine (mg/dL)	1.0 ± 0.17	0.9 ± 0.2	0.17
γ-GT (U/I)	58 ± 46.4	34.5 ± 23.9	0.03*
Prolactin (ng/mL)	7.3 ± 9.2	15.3 ± 17.0	0.04*
Cortisol (μ/dL)	27.9 ± 7.6	22.1 ± 7.4	0.01*

Data are presented as means ± standard deviations

HDL high-density lipoprotein, *LDL* low-density lipoprotein, *STGO* glutamic oxaloacetic transaminase, *SGPT* glutamic-pyruvic transaminase, *γ-GT* gamma-glutamyltransferase

* Statistically significative difference between groups

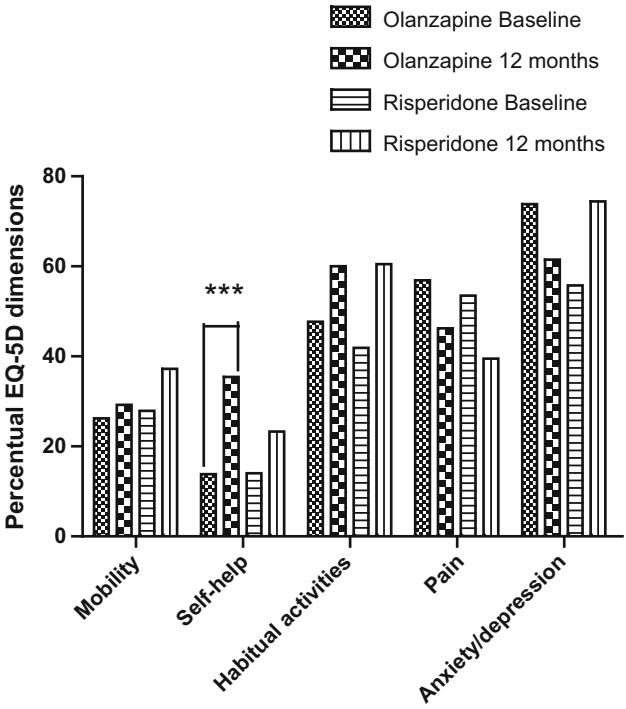

Fig. 1 Percentages of olanzapine (65) and risperidone (43) users with problems (scores of 2 or 3) in EQ-5D dimensions of quality of life at baseline and 12 months

Table 4 Mean quality-adjusted life year data for olanzapine (65) and risperidone (43) users based on the regression model adjusted by gender

Drug	Mean	Standard error	95 % confidence interval	*p* value
Olanzapine	0.665	0.038	0.590, 0.740	0.032
Risperidone	0.787	0.050	0.686, 0.887	

than among risperidone users (Table 5). Statistically significant differences in UKU Side Effect Rating Scale scores were observed for the following items: asthenia/lassitude/fatigue (higher among olanzapine users, $p = 0.02$), dystonia (higher among olanzapine users, $p = 0.01$), tremor (higher among olanzapine users, $p = 0.03$), gynecomastia (higher among risperidone users, $p < 0.02$), amenorrhea (higher among risperidone users, $p < 0.03$) ejaculatory dysfunction (higher among risperidone users, $p < 0.02$) and erectile dysfunction (higher among risperidone users, $p < 0.02$) (Table 6).

Discussion

In Brazil, improved access to care and therapeutic options have resulted in a shift in the treatment of mental illnesses [19]. Policies adopted by the Brazilian government have improved access to antipsychotic medication for mentally ill patients; for example, the

Table 5 Mean Simpson–Angus Rating Scale scores for olanzapine (65) and risperidone (43) users at the final assessment after 12 months of treatment

Characteristic	Olanzapine	Risperidone	*p*
Gait	0.44 ± 0.70	0.42 ± 0.20	0.01*
Arm dropping	0.56 ± 0.89	0.33 ± 0.56	0.29
Shoulder shaking	0.37 ± 0.88	0.83 ± 0.28	0.12
Elbow rigidity	0.33 ± 0.73	0.83 ± 0.28	0.11
Wrist rigidity	0.44 ± 0.97	0.00 ± 0.00	0.03*
Leg pendulousness	0.33 ± 0.78	0.13 ± 0.34	0.22
Head dropping	0.22 ± 0.64	0.00 ± 0.00	0.08
Glabella tap	0.04 ± 0.19	0.42 ± 0.20	0.93
Tremor	0.67 ± 0.55	0.25 ± 0.44	0.00*
Salivation	0.37 ± 0.49	0.17 ± 0.38	0.10
Total score	0.38 ± 0.54	0.11 ± 0.14	0.02*

Data are presented as means ± standard deviations

* Significant difference between groups

Table 6 Mean Udvalg for Kliniske Undersøgelser (UKU) Side Effect Rating Scale scores for olanzapine (65) and risperidone (43) users after 12 months of treatment

UKU scale item	Olanzapine	Risperidone	*p*
Psychic side effects			
Difficulty concentrating	1.04 ± 0.76	0.58 ± 0.72	0.33
Asthenia/lassitude/fatigue	0.85 ± 0.72	0.42 ± 0.58	0.02*
Somnolence/sedation	0.70 ± 0.82	0.38 ± 0.71	0.13
Memory difficulties	0.89 ± 0.93	0.75 ± 0.85	0.58
Depression	0.78 ± 0.80	0.71 ± 0.86	0.77
Tension/restlessness	0.63 ± 0.79	0.88 ± 0.85	0.29
Increased duration of sleep	0.96 ± 1.1	0.75 ± 1.07	0.49
Decreased duration of sleep	0.59 ± 1.80	0.50 ± 0.83	0.81
Increased dream activity	0.56 ± 1.76	0.17 ± 0.48	0.28
Emotional indifference	0.48 ± 0.75	0.17 ± 0.38	0.06
Neurological side effects			
Dystonia	0.19 ± 0.56	0.00 ± 0.00	0.01*
Rigidity	0.44 ± 0.64	0.29 ± 0.46	0.33
Hypokinesia/akinesia	0.23 ± 0.51	0.08 ± 0.28	0.21
Hyperkinesis	0.74 ± 0.38	0.13 ± 0.45	0.67
Tremor	0.70 ± 0.67	0.33 ± 0.48	0.03*
Akathisia	0.33 ± 1.73	0.42 ± 0.20	0.39
Epileptic seizures	0.00 ± 0.00[a]	0.00 ± 0.00[a]	
Paraesthesia	0.70 ± 1.79	0.29 ± 0.55	0.27
Autonomic side effects			
Change in visual accommodation	0.26 ± 0.59	0.17 ± 0.38	0.51
Increased salivation	0.59 ± 0.93	0.33 ± 0.70	0.26
Decreased salivation	0.85 ± 1.80	4.17 ± 0.72	0.27
Nausea/vomiting	0.27 ± 0.45	0.13 ± 0.45	0.26
Diarrhoea	0.04 ± 0.20	0.42 ± 0.20	0.96
Constipation	0.62 ± 1.02	0.29 ± 0.62	0.18
Voiding disorders	0.15 ± 0.54	0.00 ± 0.00	0.16

Table 6 continued

UKU scale item	Olanzapine	Risperidone	*p*
Polyuria/polydipsia	0.96 ± 0.82	0.63 ± 0.88	0.17
Orthostatic dizziness	0.27 ± 0.53	0.17 ± 0.48	0.48
Palpitations/tachycardia	0.35 ± 0.70	0.29 ± 0.62	0.77
Increased tendency to sweat	0.19 ± 0.49	0.17 ± 0.48	0.85
Other side effects			
Erythema	0.38 ± 1.77	0.00 ± 0.00	0.28
Morbilliform erythema	1.04 ± 2.93	0.00 ± 0.00	0.83
Petechial rash	1.04 ± 2.93	0.00 ± 0.00	0.83
Urticarial erythema	1.08 ± 2.92	0.00 ± 0.00	0.72
Psoriatic erythema	1.04 ± 2.93	0.00 ± 0.00	0.83
Erythema (unclassified)	1.04 ± 2.93	0.00 ± 0.00	0.83
Itch	0.23 ± 0.71	0.17 ± 0.38	0.69
Photosensitivity	0.46 ± 0.65	0.46 ± 0.66	0.99
Increased pigmentation	0.00 ± 0.00	0.13 ± 0.45	0.19
Weight gain	0.42 ± 0.86	0.38 ± 0.88	0.85
Weight loss	0.63 ± 1.76	0.17 ± 0.38	0.19
Menorrhagia	8.64 ± 1.71	9.00 ± 0.00	0.33
Amenorrhea	8.48 ± 1.73	6.47 ± 3.13	0.03*
Galactorrhea	9.00 ± 0.00[a]	9.00 ± 0.00[a]	
Gynecomastia	2.00 ± 3.81	5.25 ± 4.5	0.01*
Increased sexual desire	0.00 ± 0.00	0.42 ± 0.20	0.33
Decreased sexual desire	0.67 ± 2.20	0.37 ± 0.88	0.60
Erectile dysfunction	2.17 ± 3.82	5.29 ± 4.49	0.02*
Ejaculatory dysfunction	2.00 ± 3.85	5.29 ± 4.49	0.02*
Orgasmic dysfunction	1.33 ± 2.90	0.71 ± 1.23	0.31
Vaginal dryness	7.46 ± 3.09	7.38 ± 3.07	0.95
Headache	0.54 ± 0.65	0.58 ± 0.78	0.83
Tension	0.33 ± 0.48	0.54 ± 0.66	0.21
Migraine	0.19 ± 0.68	0.08 ± 0.41	0.52
Other	0.41 ± 1.74	0.042 ± 0.20	0.29
Physical dependence	7.58 ± 2.98	8.38 ± 2.123	0.28
Psychic dependence	0.37 ± 0.69	0.13 ± 0.34	0.12

Data are presented as means ± standard deviations

* Significant difference between groups

[a] Can not be computed because the standard deviations of both groups are 0

Specialised Programme for Pharmaceutical Assistance, part of the national health system, was created in 2010 to ensure the completeness of drug treatment in outpatients whose care is defined in Therapeutic Guidelines and Clinical Protocols [20]. In addition, Ordinance 364 (Clinical Therapy Guideline—Schizophrenia) stipulates that all antipsychotic drugs except clozapine may be used in the treatment of schizophrenia, with no order of preference [21]. Given the continued growth of health expenditures, the emergence of new technologies, and changes in the epidemiological profile of the population, the evaluation

of health technologies is necessary. Current Brazilian Constitution was promulgated on October 5, 1988. It stipulated the following basic guidelines for Brazil's Unified Health System (SUS): decentralisation, with a single management point in each sphere of government; comprehensive care, including curative and primarily preventive care activities; and community participation, i.e. the exercise of social control over activities and public health services. The Department of Technology Assessment in Health is a tool used to ensure adherence to these three basic principles of the SUS. The EQ-5D, a generic multidimensional instrument developed by a European research team to assess health status, can also be used in decision making regarding health technologies. Assessment of the health gains achieved by the use of atypical antipsychotic medication, considered to be a technological innovation, is essential.

We observed that self-care became a significant problem among olanzapine users during the 1-year study period. The percentages of individuals with problems in the other dimensions of quality of life did not differ significantly between timepoints, but increases in the percentages of olanzapine users with problems in the mobility and habitual activities domains were noted. These impairments in the quality of life of olanzapine users may be explained by a constellation of anthropometric and clinical variables. Most (67.7 %) users of this drug were male, and men in this study showed increased waist circumference, hip circumference, weight, waist-to-hip ratio, and systolic and diastolic blood pressure. Olanzapine users had increased triglycerides and reduced HDL cholesterol level. According to the criteria of the Brazilian Society of Metabolic Syndrome [22], these characteristics of olanzapine users in this study suggest metabolic syndrome.

Other studies have associated anthropometric and biochemical changes with the use of olanzapine [23, 24]. The application of the Simpson–Angus and UKU scales in this study confirmed the presence of extrapyramidal effects in olanzapine compared with risperidone users. These results differ from those of Soya and Gilanipoor [25], who found a greater prevalence of extrapyramidal side effects among risperidone users.

We believe that risperidone is administered predominantly to women because of expected adverse hormonal effects in men. Unlike olanzapine, risperidone was not found to significantly impair quality of life in this study, and QALY values indicated that risperidone users were able to perform activities of daily life with freedom from pain and mental disturbance. The only significantly altered hormonal variable in risperidone users was prolactin; this effect was expected and associated with significant increases in symptoms measured by the UKU scale, such as amenorrhea, gynecomastia, erectile dysfunction, and ejaculatory dysfunction.

Although both groups of patients had low educational levels and family incomes, only olanzapine users had impaired quality of life, which can be explained in part by the adverse motor, biochemical, and hormonal effects that characterise metabolic syndrome.

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