Olanzapine Versus Risperidone in Newly Admitted Acutely Ill Psychotic Patients

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Objective: Risperidone and olanzapine are the 2 most widely prescribed second-generation antipsychotics. The purpose of this study was to compare the efficacy of risperidone and olanzapine using duration of hospitalization as the primary outcome measure. This outcome was selected as it is an indirect measure of how well patients are responding to the medication and represents a "real world" endpoint relevant to practicing hospital psychiatrists.

Method: The study was done at a large state psychiatric hospital in North Carolina from 2001 to 2003. Subjects were eligible for inclusion if they required treatment with an antipsychotic (e.g., positive symptoms) and were able to provide informed consent. Eighty-five patients entered the study and were randomly assigned to risperidone (N = 40) or olanzapine (N = 45) as their initial antipsychotic. Treatment was naturalistic, and dosing was based on the discretion of the treating physician.

Results: There was no significant difference in the mean durations of hospitalization for the risperidone group (7.9 days) as compared to the olanzapine group (8.1 days). There were no significant differences in the demographics of either treatment group, but, during the study, risperidone-treated patients used more antihistamines ($\chi^2 = 4.0$, $p = .05$). Eighty percent of each group (N = 36, olanzapine; N = 32, risperidone) remained on the study medication at discharge.

Conclusions: Risperidone and olanzapine were equally efficacious, suggesting that measures other than "efficacy" (e.g., side effects, cost) should be considered when determining overall "effectiveness" of treatment.

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The atypical or second-generation antipsychotics are now considered as a first-line treatment for psychotic illnesses.[1–3] The 2 most widely prescribed second-generation antipsychotics are risperidone and olanzapine.[4] Quetiapine, clozapine, ziprasidone, and aripiprazole, the other available second-generation antipsychotics, currently have a much smaller share of the antipsychotic drug market.[5]

There are a small number of controlled trials that directly compare the efficacy of risperidone and olanzapine in the nongeriatric adult population. Efficacy measures vary from study to study, with areas of focus including positive symptoms, negative symptoms, and cognitive functioning. Four studies found no difference between the 2 agents,[6–9] 6 identified superiority of olanzapine in at least 1 outcome measure,[10–15] 1 identified superiority of risperidone in at least 1 outcome measure,[16] and another study revealed mixed results depending on the cognitive domain measured.[17] Overall, these studies differed considerably in their design, with a lack of uniformity among outcome measures, sample sizes, patient populations, medication doses, and trial duration. The statistical superiority of 1 medication over the other when found was typically small in magnitude, often with questionable clinical significance. A recent review of the randomized, blinded studies concluded that there were no clinically meaningful differences in efficacy between risperidone

and olanzapine,[18] and a meta-analysis revealed no differences in efficacy among amisulpride, risperidone, and olanzapine.[19]

The data describing the incidence and prevalence of side effects, both from controlled studies and other available data, more clearly distinguish the 2 medications.[20] Risperidone is more likely to be associated with extrapyramidal side effects, particularly at doses greater than 6 mg/day,[21] prolactin elevation,[22,23] and impairments in sexual functioning.[24] Olanzapine, on the other hand, appears to have a greater propensity for weight gain,[25–27] dyslipidemia,[28] and glucose dysregulation.[29,30]

The purpose of this study was to compare the efficacy and side effects of risperidone versus olanzapine when administered to newly admitted, acutely ill patients with psychosis. The duration of hospitalization was selected as the primary outcome measure of efficacy, since it is an indirect measure of how well patients are responding to the medication and represents a "real world" endpoint relevant to practicing hospital psychiatrists.

METHOD

The study was conducted at Dorothea Dix Hospital, a state psychiatric facility located in Raleigh, N.C., during the years 2001 through 2003. All patients described in this report were newly admitted acutely ill patients to the adult psychiatry service of the hospital. The hospital serves 16 counties in the south central region of North Carolina. Patients are typically admitted owing to violent behavior, directed at either themselves or others, with approximately 95% admitted involuntarily.

Patients during the study period were referred from either local outpatient mental health centers (43%) or an emergency department of a community hospital (46%), with a smaller number either transferred from another hospital's inpatient unit or self-referred (11%). These are acute care patients, the vast majority of whom have not received antipsychotic treatment at another facility prior to admission to this hospital.

Patient eligibility was broad, with limited restrictions to patient inclusion. The intent was to recruit patients 18 to 60 years old who would typically be offered either risperidone or olanzapine as a routine treatment based on the clinical impression of the admitting psychiatrist (e.g., the presence of positive symptoms of psychosis). Exclusion criteria were limited to (1) an inability to give informed consent at the time of admission, (2) a history of allergy or significant adverse event from either risperidone or olanzapine, (3) a lack of previous benefit from either risperidone or olanzapine, (4) no need of an antipsychotic medication, (5) a clinical need for treatment with either haloperidol or fluphenazine long-term injections upon discharge due to a history of noncompliance, or (6) an inability to obtain either risperidone or olanzapine upon discharge.

All patients admitted during this time period were screened for eligibility and willingness to participate. Patients who agreed to participate and who were able to give informed consent were randomly assigned to open treatment with either risperidone or olanzapine as their initial antipsychotic treatment. The admitting psychiatrists were instructed to choose the dose and any needed concomitant medications in accordance with normal clinical practice. For comparison purposes, we also reviewed 1599 consecutive acute adult admissions that occurred during a 6-month period (May 1, 2003, through November 30, 2003) to determine gender, diagnosis, and length of stay.

This study was approved by the Committee for the Protection of the Rights of Human Subjects at the University of North Carolina at Chapel Hill. The study was funded by a grant from the Stanley Medical Research Institute.

Eighty-five patients agreed to participate in the protocol. During the recruitment period, approximately 3000 patients were admitted to the hospital who were psychotic and in need of antipsychotic treatment. Most of these patients were not willing to participate in the research protocol, were not able to give informed consent, or were not willing to take any medication.

Statistics

Sample size constraints limited the power of this study primarily to a comparison of mean hospitalization time for those initiated on each study drug, olanzapine and risperidone. Duration of hospitalization was calculated for each subject regardless of whether he/she remained on the study medication. Statistical analysis was performed using Poisson regression and a Pearson χ^2 test, whereby the p values were quoted for a 95% confidence level. Poisson regression is used because this distribution is most representative of the skewed non-normal hospitalization times. Length of stay comparisons of the study group to the all acute adult admissions group were done using Student t test.

RESULTS

Baseline Demographics

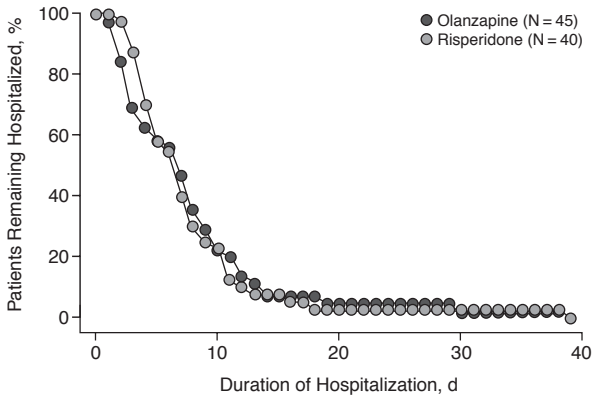
There were no statistically significant differences between the patients randomly assigned to risperidone or olanzapine in terms of age, gender, ethnicity, and discharge diagnosis (Table 1). Eighty percent of each patient group (36/45 for olanzapine, 32/40 for risperidone) were discharged on the randomly assigned medication. The mean ± SD discharge doses were 12.4 ± 5.6 mg for olanzapine (N = 36) and 3.4 ± 2.1 mg for risperidone (N = 32). When we examined only patients diagnosed with a DSM-IV major mental illness (schizophrenia; schizoaffective disorder; bipolar disorder; major depressive disorder, severe, with psychotic features; schizophreniform

Table 1. Demographics of Patients With Psychosis Randomly Assigned to Olanzapine or Risperidone[a]

Characteristic	Olanzapine (N = 45)	Risperidone (N = 40)
Age, y		
Mean	33.8	32.0
Range	53 – 18 = 35	52 – 19 = 33
Gender		
Male	38	33
Female	7	7
Ethnicity		
White	15	10
African American	27	27
Other	3	3
DSM-IV discharge diagnosis		
Schizophrenia; schizoaffective disorder; bipolar disorder; major depressive disorder, severe, with psychotic features; schizophreniform disorder; psychotic disorder NOS	35	33
Substance abuse, substance-induced psychosis	9	6
Mood disorder NOS	1	1

[a]No significant differences, Pearson χ^2 test.
Abbreviation: NOS = not otherwise specified.

Figure 1. Percentage of Patients With Psychosis Remaining Hospitalized Over Time Who Were Treated With Olanzapine or Risperidone[a]



[a]There was no significant difference in the survival curves (Poisson regression for duration of hospitalization, p = .87).

Table 2. Use of Specific PRN and Standing Medications Among Patients With Psychosis Randomly Assigned to Treatment With Olanzapine or Risperidone

PRN and/or Standing Medication	Olanzapine (N = 45)	Risperidone (N = 40)
None	15	16
Benztropine and/or trihexyphenidyl	2	5
Diphenhydramine and/or hydroxyzine*	4	10
Divalproex, lithium, gabapentin, carbamazepine, haloperidol, quetiapine, ziprasidone, citalopram, escitalopram, venlafaxine, paroxetine, fluoxetine, sertraline, mirtazapine, and/or amitriptyline/perphenazine	2	7
Trazodone	5	7
Lorazepam and/or clonazepam	27	17

*χ^2 = 4.0, p = .05; all other comparisons not significant.

disorder; and psychotic disorder not otherwise specified) who were discharged on study medication, the discharge doses were 12.2 ± 5.5 mg for olanzapine (N = 30) and 3.3 ± 1.4 mg for risperidone (N = 28).

Duration of Hospitalization

There was no statistically significant difference in the principal outcome measure, the duration of hospitalization, for the whole sample (Figure 1; Poisson regression for duration of hospitalization, p value for hypothesis of means being different = .87). The mean ± SD duration of hospitalization for olanzapine-treated patients was 8.1 ± 7.1 days; for risperidone-treated patients, 7.9 ± 6.2 days. When we examined only patients with a major mental illness (as defined above), there was still no significant difference in the mean duration of hospitalization between the 2 treatments (olanzapine [N = 35] = 8.8 ± 7.8 days; risperidone [N = 33] = 8.3 ± 6.5 days; Poisson regression for duration of hospitalization, p = .55).

Concomitant Medications

There was no statistically significant difference between the 2 groups in the number of patients receiving p.r.n. medications (olanzapine, N = 30; risperidone, N = 24) or other standing medications (olanzapine, N = 29; risperidone, N = 30), nor a difference in the duration of hospitalization for these groups (Poisson regression for duration of hospitalization, p = .75). Table 2 shows the types of concomitant medications used for each study group. The only significant difference found was that risperidone-treated patients were more likely to be prescribed concomitant antihistamines (χ^2 = 4.0, p = .05).

Comparison to All Acute Admissions Patients

Demographic comparison of the study group to a group of 1599 consecutive acute adult admissions patients revealed a significant difference in sex (study group: 83.5% male, 16.5% female; all acute admissions: 61.4% male, 38.6% female; χ^2 = 12.2, p < .001). Age and ethnicity did not differ. The mean ± SD length of stay for acute admissions patients with a major mental illness (as defined above; N = 575) was 15.6 ± 39.2 days. The mean ± SD length of stay for acute admissions patients with other (nonpsychotic) illnesses (N = 1024) was significantly less (3.7 ± 6.1 days; t = 9.5, df = 1597, p < .001). Comparison of the length of stay of all (both risperidone and olanzapine, N = 68) study patients with a major mental illness (8.5 ± 7.1 days) with the length of stay for all acute admissions patients with a major mental illness (15.6 ± 39.2 days) did not show a significant difference (t = 1.5, df = 641, p = .137); however, these study patients had a significantly longer length of stay

than nonpsychotic acute admissions patients ($t = 6.2$, $df = 1090$, $p < .001$).

DISCUSSION

Overall, these results are consistent with what has previously been published about the differences in efficacy between risperidone and olanzapine.[18,19] The medications were very comparable with no difference found on the time interval from admission to discharge. Furthermore, duration of hospitalization did not differ between the 2 groups even when assessing only those diagnosed with a major mental illness (i.e., excluding primary substance abuse or mood disorders without psychosis). Use of p.r.n. medications did not vary between the 2 groups except for use of antihistamines; i.e., patients randomly assigned to risperidone were more likely to have an antihistamine prescribed. The doses used in our study are comparable to those in other naturalistic studies of antipsychotic use.[16,31]

Our results differ from other reports comparing length of stay between patients taking risperidone or olanzapine.[32,33] In those reports, patients treated with risperidone were discharged more quickly than those treated with olanzapine. However, in those studies, medication was not randomly assigned, and thus selection bias may have been introduced. In the present study, medication was randomly assigned, and patients therefore provided informed consent. Another potential explanation for the discrepant findings is a markedly different patient population and/or type of clinical practice between past studies[32,33] and our study. Our patient population differs from populations of some other state hospitals in that virtually none of our adult admissions patients have received significant recent treatment elsewhere; i.e., they are acute care patients. As a consequence, in our study, more than 90% of patients were discharged within 30 days. In the Kelly et al. study,[32] only 32% to 45% were discharged within 30 days, and in the Taylor et al. study,[33] the average length of stay was 49 to 58 days.

When the use of concomitant medications was compared, only antihistamines differed significantly, with patients initiated on risperidone having greater use. This difference may in part be related to risperidone having less intrinsic antihistamine effect than olanzapine. In our hospital practice, antihistamines are usually prescribed for insomnia, suggesting the possibility that risperidone-treated patients more often required medication for sleep. There was a numerical, though not statistically significant, difference in the use of benzodiazepines between the 2 treatment groups, with olanzapine-treated patients more often receiving benzodiazepines than risperidone-treated patients. Benzodiazepines are used for a variety of reasons in our hospital, but are primarily used for anxiety, agitation, insomnia, and alcohol detoxification. It is therefore difficult to assign a particular reason for this numerical difference given the limitations of our data collection.

Of interest, while not statistically significant, the study patients had numerically shorter lengths of stay with less variance than the complete group of acute admissions patients with a major mental illness, suggesting that the study group may represent a "good responder" group. This concept is supported by the study group's ability and willingness to provide informed consent at admission. However, patients with a major mental illness had significantly longer lengths of stay as compared to acute admissions patients without psychotic illness. This result demonstrates that length of stay varied with diagnostic (clinical) condition rather than administrative or financial factors.

There are limitations to these data. First, we used duration of hospitalization as our principal outcome measure rather than a conventional rating scale. The rationale for choosing this outcome measure is that time to discharge from the hospital represents a clinically meaningful measure of psychiatric stability; that is, patients are deemed well enough that they can return to community living. In contrast, statistically significant differences on rating scales may exist between treatments and yet have limited clinical significance. Second, we were able to recruit only a minority of patients that were potentially eligible to participate. This is not an unusual problem in clinical research but is one that could impair the generalizability of the results. Third, the sample size may not have been large enough to detect small differences in the efficacy measures. However, we would again question whether small differences found in very large samples (though statistically significant) are clinically meaningful. Fourth, there were no formal evaluations of extrapyramidal symptoms during the study. Lastly, given the relatively short duration of hospitalization, we could not accurately assess weight change, the development of dyslipidemia, or glucose dysregulation and the onset of type II diabetes mellitus.

Given that these and other data suggest that the choice of antipsychotic does not appear to significantly alter length of hospitalization or other measures of effectiveness or efficacy, other considerations may be of greater importance when determining the choice of antipsychotic to prescribe. As noted above, there are clear differences in the side effect profiles of risperidone and olanzapine.[20] Additionally, in most settings, the direct costs of olanzapine are usually higher than those of risperidone.[32–35] For example, despite similar numbers of patients treated in fiscal year 2003–2004, our hospital costs for olanzapine were 1.58 times greater than for risperidone (US $531,960.47 vs. $337,143.63). It should be noted that in other studies in which total health care costs were evaluated, overall cost savings with olanzapine use were

shown.[36–38] Still, careful consideration of side effect profile and cost of or access to medications becomes an important part of the decision tree when choosing an antipsychotic medication.

Drug names: aripiprazole (Abilify), benztropine (Cogentin and others), carbamazepine (Tegretol, Carbatrol, and others), citalopram (Celexa), clonazepam (Klonopin and others), clozapine (Clozaril, FazaClo, and others), diphenhydramine (Benadryl and others), divalproex (Depakote), escitalopram (Lexapro), fluoxetine (Prozac and others), fluphenazine (Prolixin and others), gabapentin (Neurontin and others), haloperidol (Haldol and others), hydroxyzine (Vistaril, Atarax, and others), lithium (Lithobid, Eskalith, and others), lorazepam (Ativan and others), mirtazapine (Remeron and others), olanzapine (Zyprexa), paroxetine (Paxil and others), quetiapine (Seroquel), risperidone (Risperdal), sertraline (Zoloft), trazodone (Desyrel and others), venlafaxine (Effexor), ziprasidone (Geodon).

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