

Comparative efficacy of haloperidol and olanzapine in patients of schizophrenia: a 6 month follow up trial

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Abstract : Present study was carried out to compare the efficacy of olanzapine and haloperidol in patients of schizophrenia. A prospective randomized, open label study carried out on patients attending the outpatient clinic or those admitted to inpatient services. 40 cases of schizophrenia diagnosed as per ICD-10 were randomized to olanzapine and haloperidol group and were assessed at 3 months and after 6 months of treatment using scales PANSS and ESRS. The study showed that both the drugs were equally efficacious in improving the psychopathology and haloperidol led to increase in extrapyramidal side effects. Both olanzapine and haloperidol are equally effective in causing clinical improvement. In comparison, both the drugs do not have much difference in the cost of treatment.

Keywords : Efficacy, Haloperidol, Olanzapine, Schizophrenia

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INTRODUCTION

Schizophrenia is a severe and disabling psychiatric disorder with devastating effects on both its patients and their families. It extracts a huge economic cost from the society. Its usual onset is in late adolescence or early adulthood, and the illness generally follows a recurrent and chronic course. Evidence from epidemiological research indicates that schizophrenia occurs in all populations with prevalence in the range of 1.4 to 4.6 per 1000 and incidence rates in the range of 0.16-0.42 per 1000 population.¹ The lifetime prevalence of suicide is about 10% in patients with schizophrenia. According to the Global Burden of Disease Study, schizophrenia causes a high degree of disability, which accounts for 1.1% of the total Disability Adjusted Life Years (DALYs) and 2.8% of Years Lived with Disability. In the World Health Report 2001, schizophrenia is listed as the 8th leading cause of DALYs worldwide in the age group 15-44 years.² Despite schizophrenia's longstanding affliction of mankind³, effective treatment for this disorder

only became available in the middle of the 20th century.⁴ Numerous landmark studies⁵⁻⁷ demonstrated clearly that chlorpromazine, the prototypic antipsychotic, was more effective than non-pharmacologic treatment (eg, placebo, psychotherapy) in alleviating the acute symptoms of schizophrenia and preventing their recurrence. Initially chlorpromazine was termed a neuroleptic drug to describe its effect of psychomotor immobilization. Haloperidol belonging to the chemical class of butyrophenones was developed in the late 1950s for use in the field of anaesthesia and was initially used to prevent surgical shock. Research subsequently demonstrated its beneficial effect on hallucinations, delusions, aggressiveness, impulsiveness and states of excitement.⁸⁻¹⁰ These findings led to the introduction of haloperidol as an antipsychotic. Hailed as a breakthrough, it was considered to be the most potent antipsychotic known, effective for a wide range of psychotic disorders and in addition, appeared to keep side effects to a minimum.¹⁰ Since its introduction, clinical

experience has suggested that haloperidol is indeed an effective antipsychotic, particularly beneficial for those who are experiencing acute hallucinations and delusions. After almost half a century, experience with conventional antipsychotic drugs has revealed their substantial limitations.

The introduction of clozapine treatment in the United States in 1990 opened the era of "atypical" antipsychotic drugs which were developed with the aim to be efficacious in treatment without carrying the burden of adverse extrapyramidal side effects which were an important determinant of treatment non-adherence. The atypical or second generation antipsychotics differ from conventional antipsychotics in their lower affinity for D2 receptors and relatively greater affinities for other neuroreceptors, including those for serotonin and norepinephrine and in their ability to modulate glutamate receptor mediated functions and behavior.¹²

Olanzapine is a novel antipsychotic displaying nanomolar affinity at D1–D4, serotonergic (5-HT₂, 3, 6), muscarinic (subtypes 1–5), adrenergic (α₁), and histaminergic (H₁) binding sites. There is extensive western literature over this issue but studies in Indian settings have been very few with little emphasis on comparability of efficacy between these two different classes of antipsychotics.

Hence the study was planned with the aim to compare the efficacy of olanzapine versus haloperidol over a period of six months.

MATERIAL AND METHODS

Patients were inducted from those attending the outpatient clinic or those admitted to the inpatient services of the Department of Psychiatry of the Government Medical College and Hospital (GMCH), Chandigarh. The informed consent from patient and close family member

was taken and study was approved by the ethical committee of the institute.

The sample consisted of 40 patients with the diagnosis of Schizophrenia according to ICD-10.¹¹ 20 patients each were assigned to haloperidol and olanzapine group based on random table.

Inclusion Criteria were patients in the age group of 18 to 65 years, fulfilling criteria for Schizophrenia as per ICD 10, with IQ in normal range.

Exclusion Criteria were patients with comorbid substance related disorders except nicotine, patients who fulfilled the criteria for Treatment Resistant Schizophrenia (TRS), which was defined as:

- a) At least two prior drug trials of at least 4-6 weeks duration at 400-600 mg of Chlorpromazine (or equivalent) without significant clinical improvement.
- b) Persistent psychotic symptoms which was defined as a score of > 45 on 18 item scale of BPRS and score of >4 (moderate) on at least two items of positive symptoms of BPRS.

Patients with past history of poor response to olanzapine or haloperidol, with pre-existing diabetes mellitus, chronic medical illness, neurological disorders-head injury, tumours, movement disorder, who were pregnant and lactating, who were unwilling to participate in the study, and patients with history of hypersensitivity reaction due to haloperidol or olanzapine in the past.

It was an open label comparative longitudinal study with an intent to treat analysis. The drugs of standard pharmaceutical companies approved by the drug committee of GMCH were prescribed.

Patients who were drug naïve or who had not been on antipsychotics in last 2 weeks were

started on either on olanzapine or haloperidol as per randomization. Efforts were made to keep the dosages of medications in the therapeutic range, that is, 5-20 mg of haloperidol and 5-20 mg of olanzapine and the treating doctor was requested to keep the same therapeutic dosage for atleast 6 weeks and in case there was no satisfactory response at the end of 6 weeks. the treating doctor was at liberty to increase the dose as needed and it was documented. Though the trial consisted of 6 months of open label therapy, patients who did not show adequate response after 3 months, that is atleast 50% reduction from baseline score of PANSS(positive and negative symptom scale for schizophrenia) were excluded from the study and started on other antipsychotics.

Concomitant medications like benzodiazepines (lorazepam, alprazolam, clonazepam) for sedation and sleep disturbances and trihexyphenidyl for counteracting extrapyramidal side effects was permitted wherever required and were recorded in both the groups.

The measure of efficacy was based on the reductions in total score of PANSS,¹³ and its subscale items score namely-positive, negative and general psychopathology subscales with 3 assessments done at 1 month, 3 months and 6 months of treatment.

Descriptive statistics were used to characterize demographic and clinical data of the whole sample. The baseline and post treatment scores were analyzed by Paired t test. Univariate analysis of variance was used for correlation purposes. Statistical significance was set at P < 0.05 level (significant) and P < 0.01 (highly significant).

RESULTS

The olanzapine and the haloperidol group were similar with regard to sociodemographic

variables namely age, sex, marital status, education, income and locality except that more patients in the olanzapine group came from nuclear families(85% v/s 50%). In both the groups the maximum patients were in the age group of 26-35 years. Male and females were equally distributed. With regards to duration of illness, in both the groups almost 60% of the patients illness was of duration 1-5 years, mean 2.29 years and there was no statistically significant difference between the two groups with regards to duration of illness.(pvalue 0.229)

Olanzapine was used in the range of 5-30 mg , mean dose of 18.5 mg and haloperidol was used in the range of 5-15 mg , mean dose of 11.275 mg. Comparison of use of concomitant drugs is given in Table 1

Table 1
Use of concomitant drugs

Use of concomitant drugs	Olanzapine group N=20 N(%)	Haloperidol group N=20 N(%)	P value
Anticholinergics	2 (10)	18 (95)	.001**
Benzodiazepines	4 (20)	17 (85)	.002*

** p value <0.01, * p value <0.05

Efficacy measures: Scores on Positive and negative symptom scale for schizophrenia (PANSS)

Table 2 shows the changes in total scores of PANSS as well as the changes in scores of its subscales which include positive syndrome scale , negative syndrome scale and the general psychopathology scale from baseline to 1 month, baseline to 3 month and baseline to 6 month as well as change from 1 month to 3 month and from 3 month to 6 month.

As can be seen from the Table 2, the p values were highly significant on changes in the total scores as well as all three subscale scores at all assessment points in both the olanzapine and the haloperidol group.

Table 2
Changes in PANSS score

Measures	Clanzapine group						Haloperidol group					
	B to 1 mth	B to 3 mth	E to 6 mth	1mth to 3mth	1mth to 6mth	3mth to 6 mth	B to 1 mth	B to 3 mth	B to 6 mth	1mth to 3mth	1mth to 6mth	3mth to 6 mth
	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean
	S.D	S.D	S.D	S.D	S.D	S.D	S.D	S.D	S.D	S.D	S.D	S.D
	P value	P value	P value	P value	P value	P value	P value	P value	P value	P value	P value	P value
Total score	-20.2 12.7	-48.1 20.7	-60.0 25.37	-27.9 11.83	-39.8 16.5	-11.9 10.9	-18.7 6.9	-36.8 11.9	-46.0 15.1	-18.1 9.9	-27.3 13.7	-9.2 8.8
	.001*	.001*	.001*	.001*	.001*	.001*	.001*	.001*	.001*	.001*	.001*	.001*
Positive syndrome score	-6.8 6.1	-16.3 10.3	-20.6 13.2	-9.5 6.99	-13.8 10.13	-4.3 5.7	-5.7 3.6	-13.8 6.7	-16.5 6.6	-8.1 5.4	-10.8 5.8	-2.7 2.7
	.001*	.001*	.001*	.001*	.001*	.003*	.001*	.001*	.001*	.001*	.001*	.001*
Negative syndrome score	-5.45 4.1	-12.7 6.9	-15.6 7.20	-7.3 4.99	-10.1 5.49	-2.9 3.9	-5.6 2.3	-9.8 5.0	-11.5 5.7	-4.2 4.2	-5.9 5.3	-2.2 3.5
	.001*	.001*	.001*	.001*	.001*	.004*	.001*	.001*	.001*	.001*	.001*	.016*
General psycho-pathology score	-8.5 5.4	-18.6 8.6	-24.4 10.7	-10.1 4.1	-15.9 6.8	-5.8 5.1	-4.3 10.1	-11.3 10.0	-15.6 11.9	-7.0 3.7	-11.3 5.4	-4.3 4.8
	.001*	.001*	.001*	.001*	.001*	.001*	.022*	.001*	.001*	.001*	.001*	.001*

* p<0.01

Table 3
Comparison of changes in PANSS scores at all assessment points between olanzapine and haloperidol group.

PANSS	B to 1 mth P value	B to 3 mth P value	B to 6 mth P value	1 mth to 3 mth P value	1 mth to 6 mth P value	3 mth to 6 mth P value
Total score	.913	.126	.120	.068	.057	.374
Positive syndrome score	.946	.415	.392	.568	.524	.874
Negative syndrome score	.662	.163	.063	.071	.072	.740
General psycho-pathology score	.192	.077	.072	.066	.097	.513

Table 4
Changes on ESRS

ESRS	Olanzapine group			Haloperidol group		
	B to 1 mth	B to 3 mth	B to 6 mth	B to 1 mth	B to 3 mth	B to 6 mth
	Mean S.D	Mean S.D	Mean S.D	Mean S.D	Mean S.D	Mean S.D
	P value	P value	P value	P value	P value	P value
Park. dysk.dystonia(subjective)	0.0 ± 1.5 1.00	0.15 ± 1.6 .679	0.4 ± 1.4 .214	4.1 ± 3.7 .001	2.8 ± 2.6 .001*	2.0 ± 1.7 .001*
Park.objective	0.3 ± 1.7 .392	0.8 ± 2.5 .176	0.8 ± 2.5 .176	5.8 ± 4.9 .001*	3.4 ± 3.0 .001*	2.4 ± 2.3 .001*
Dystonia.objective	-	-	-	-	-	-
Dysk.objective	-	-	-	-	-	-
CGI.park.	0.0 ± 1.5 1.06	0.12 ± 1.3 .798	0.6 ± 1.8 .248	3.1 ± 3.7 .045*	2.8 ± 2.8 .029*	2.0 ± 1.7 .098
CGI.dystonia	-	-	-	-	-	-
CGI.dysk.	-	-	-	-	-	-
CGI.akathisia	-	-	-	-	-	-

As can be seen from the table, the comparison of changes in total score and the three subscale scores between the olanzapine and haloperidol group did not reach statistical significance at all assessment points.

Scores on Extrapyramidal symptom rating scale(ESRS)

The changes in ESRS is along its domains namely, parkinsonism, dystonia and dyskinesia (subjective) score, parkinsonism (objective) score, dystonia (objective) score and dyskinesic movements (objective) score and clinical global impression of dyskinesia, parkinsonism, akathisia and dystonia.

Table 4 show changes in ESRS domains from from baseline to 1 month, to 3 month and to 6 month as well as change from 1 month to 3 month and from 3 month to 6 month

As can be seen from the table, there were no statistically significant changes in the scores of parkinsonism (both subjective and objective examination) at all assessment points in the olanzapine group. There were no incidence of dyskinesic and dystonic movements on objective examination at all assessment points.

But in the haloperidol group, there were statistically significant changes in the scores of

parkinsonism(both subjective and objective examination) at all assessment points. There were no incidence of dyskinesic and dystonic movements on objective examination at all assessment points.

Table 5

Comparison on ESRS scores between the two groups

ESRS	B to 1 m th P value	B to 3 mth P value	B to 6 mth P value
Park.sub	.002**	.002**	.0001**
Park.obj	.002**	.002**	.0001**

** p<0.01 * p<0.05

As can be seen from the Table 5, p values are statistically significant in favour of haloperidol group with regards to the mean increase in scores in domains of ESRS namely, parkinsonism subjective and objective examination across all assessments points.

DISCUSSION

The present study was carried out to compare the efficacy of olanzapine versus haloperidol in patients of schizophrenia. The present study was a prospective, randomized, open label trial with an intent to treat analysis in which patients who were drug naïve or who had not been on antipsychotics for atleast 2 weeks were started either on olanzapine or haloperidol as per randomization. The doses of olanzapine were in the range of 5-30 mg(mean dose 18.5 mg) and doses of haloperidol were in range of 5-15 mg(mean dose 11.275 mg). All patients were assessed at baseline, at the end of 1 month, at the end of 3 months and at the end of 6 months using the PANSS. The majority of efficacy studies of the atypical antipsychotics that have been reported relate to symptom improvement in short-term clinical trials of less than 12 weeks in duration.^{14,17,18} However, schizophrenia is often both a chronic and recurrent disorder and hence information on efficacy in long-term maintenance treatment is important. Hence, our study followed

up the patients for upto 6 months which is a fairly long follow up in Indian settings.

There was significant improvement on PANSS total score, positive syndrome, negative syndrome and general psychopathology subscale scores at all points of comparisons in the study in both olanzapine group and the haloperidol group. On comparison of the improvement in PANSS scores, the improvement on total as well as the 3 subscale scores in olanzapine group was more as compared to haloperidol but this difference failed to reach statistical significance at all assessment points. Hence, the two drugs were equally efficacious in improving symptoms when assessed with PANSS. These findings are in concordance with findings of a double blind randomized control trial¹⁴ comparing olanzapine and haloperidol in patients of schizophrenia which found substantial but comparable baseline-to-endpoint reductions in symptom severity in both the groups, when followed up for a period of 104 weeks. Similarly, a meta-analysis of three trials comparing olanzapine with haloperidol showed that changes in positive and negative symptom scores did not differ significantly between the two drugs.¹⁵

Another study examined the effectiveness of olanzapine and haloperidol in patients experiencing their first episode of a schizophrenia-related psychotic disorder over a 2-year treatment period.¹⁶

Olanzapine and haloperidol treatment were both associated with comparable reductions in symptom severity over the course of the study.

Similarly in a 12-month, multi-center, double-blind comparison of flexibly-dosed olanzapine and haloperidol in severely ill patients with schizophrenia, authors found that olanzapine and haloperidol did not differ in measures of efficacy.¹⁷ Similar results were obtained in an open label trial of 12 weeks duration on Indian patients where improvement in total and positive syndrome

scores of PANSS was similar in patients on either olanzapine or haloperidol.¹⁸ However, in the study, olanzapine showed superior improvement on negative symptoms and secondary depressive features. This superiority of olanzapine in improving negative symptoms was not found in our study. The perceived benefits of atypical antipsychotics on negative symptoms may result primarily from decreasing the burden of extrapyramidal adverse effects rather than better efficacy for core negative symptoms.¹⁹

The most recent trial comparing second generation antipsychotic drugs (olanzapine, ziprasidone, quetiapine, amisulpride) with low-dose haloperidol in first-episode schizophrenia also found comparable reductions in PANSS scores at end of 1 year.²⁰ However, this study used haloperidol in dose ranges of 1-4 mg which was much less than the dose used in our study (5-15 mg). It has been hypothesized that low doses of antipsychotics suffice in first episode patients because first-episode patients have little exposure to antipsychotic medications, and so their dopaminergic system may be more sensitive to antipsychotic medication. The similar efficacy of haloperidol and olanzapine found in our study is also echoing the findings of recent large, multicentre randomized double blind, industry independent controlled trials^{21,22} conducted in the west in real world settings that typical and atypical antipsychotics are largely equally efficacious and it is the side effect profile that determines issues like discontinuation of treatment. This similar efficacy is of importance in a developing country like ours where the cost effectiveness of drugs is relevant and important in issues of compliance and subsequent long term management of patients. Hence we can observe that though various claims have been made with regard to the superiority in efficacy and safety of the atypical antipsychotics as compared to the conventional drugs, this has precipitated an important debate that is now underway regarding

the appropriate role of the atypical antipsychotics in treating schizophrenia. The debate concerns the relative efficacy, the comparative side effects, their effectiveness for patients in everyday settings and their cost-effectiveness. The results from various studies have been conflicting. In the western market, the atypical antipsychotics cost considerably more than the conventional drugs they may replace.

The average cost of olanzapine was approximately Rs.1260 and that of haloperidol was approximately Rs.1080. but due to the addition of trihexyphenidyl which was used in haloperidol group, the cost in this group was approximately Rs.1700. If the additional costs of typical antipsychotics in our setting are not justified by their benefits, this information could significantly influence clinicians in their decision making in prescribing antipsychotics. There have been increasing focus on testing the efficacy of antipsychotics in real-world settings that would mirror routine clinical care without strict inclusion criteria and non-industry sponsored in order to enhance the credibility of the study.

Though the present study was conducted using sound methodology and strict inclusion criteria, there are certain limitations. 1) The study had a small sample size. 2) It was an open label trial and no blinding was done, hence personal bias of information cannot be ruled out. 3) We did not compare the discontinuation rates and reasons for discontinuation of patients who dropped out from the treatment which could have been an important outcome measure of comparison between the two drugs.

In Conclusion conventional antipsychotic drugs are believed to be cheaper than the atypical antipsychotic drugs. Thus, majority of the dispensaries in government hospitals still dispense conventional antipsychotics including chlorpromazine, haloperidol and trifluoperazine with the assumption of cost reduction. The findings of

the study demonstrate that conventional antipsychotic drugs are not cheaper, maybe slightly costlier than the atypicals. The study also supports the fact that conventional antipsychotics lead to troublesome extrapyramidal side effects which are subjectively as well as objectively causing social embarrassment for the patients. On the other hand, atypicals are not as safe as they were thought to be. Treatment emergent metabolic syndrome with atypicals is a major cause of concern for health professionals. They have started facing a dilemma of addressing the cost benefit and cost effectiveness.

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