Original Research Article

A prospective randomized comparative study of sexual side effects of Risperidone, Iloperidone and Amisulpride in patients with psychosis

Priya Janardhan[1], Anil Kumar Mysore Nagaraj[2*], Basavanna PL[3], Narendra Kumar M S[4]

[1]Medical Advisor, Biocon Biologics Ltd, Bengaluru, INDIA.
[2]Specialist IMG, North West Area Mental Health Services, Melbourne Health, Melbourne, AUSTRALIA.
[3]Professor of Pharmacology, Mysore Medical College and Research Institute, Mysore, INDIA.
[4]Assistant Professor, Department of Psychiatry, Mysore Medical College and Research Institute, Mysuru, INDIA.
Email: nagarajakm24@gmail.com

Abstract

Background: The antipsychotics Risperidone and Iloperidone are benzisoxazole derivatives that are structurally different and metabolized differently. Amisulpride is a member of the class of benzamide and hence structurally different from the other two. Having a role in prolactin secretion, they all are implicated in sexual dysfunction. We wish to study this on Indian population. **Methods:** It is a prospective randomized comparative study having three visits, on day 1, 21 and 42. Sixty patients with psychosis, 20 each randomized to Risperidone, Iloperidone and Amisulpride were compared for sexual dysfunction using UKU side effect rating scale, and were analysed using descriptive and comparative statistical tests. **Results:** Fifteen percent of subjects on Risperidone, 20% on Iloperidone and none on Amisulpride reported sexual dysfunction on the UKU side effect rating scale at the end of 6 weeks. All of them reported problems with desire (increased or diminished) and none reported problems in other phases of sexual dysfunction. There was no significant difference in the frequency of desire changes among the study drugs, however within the group, the change in mean score from 2nd to 3rd visit significantly differed with Iloperidone. The scores actually reduced thus indicating improvement. **Conclusions:** The study reveals that during the acute phase treatment, all the three antipsychotic medication are relatively safe with respect to sexual side effects. However Iloperidone seemed to affect the desire more frequently than the other medication.

Keywords: sexual side effect.

***Address for Correspondence:**
Dr. Anil Kumar Mysore Nagaraj, Specialist IMG, North West Area Mental Health Services, Melbourne Health, Melbourne, AUSTRALIA.
Email: nagarajakm24@gmail.com

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INTRODUCTION

Psychosis is a clinical syndrome describing the state of mind involving abnormal thoughts and perceptions and loss of contact with reality. It is one of the defining features of schizophrenia. However there are other different types of psychotic disorders such as Acute and Transient Psychotic Disorder, Delusional disorder, Schizoaffective disorder and unspecified nonorganic psychosis (as per ICD 10). The overall prevalence of people meeting criteria for diagnosis of an ICD-10 psychotic disorder is 3.1 %.[1] Antipsychotics are the main stay in the treatment of psychoses. One of the new challenges in the pharmacological management of psychoses is to choose among the newer second generation antipsychotic drugs (SGAs) or Atypical antipsychotics. SGAs have the potential to increase weight, alter the glycemic profile and lipid parameters and cause sexual dysfunction.[2] The choice of antipsychotic drugs for long term treatment of psychosis is based primarily on minimizing the adverse effects and

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improving the compliance. No antipsychotic is absolutely free of side effects, especially in the long term prophylactic treatment. However some of them, mainly the first generation antipsychotics (FGAs) like haloperidol can cause serious and at times life threatening side effects like laryngeal dystonia within days of initiation. The development of adverse events can undermine treatment response and relapse prevention. Thus minimising adverse effects is beneficial to improve treatment compliance and prevent relapse.[3] This might be relevant even in case of first episode psychosis or the acute and transient psychosis where the duration of treatment is relatively shorter. Sexual dysfunction (SD) is a common side effect of antipsychotic medication. It is a distressing adverse effect that can lead to poor medication adherence. It includes any reduction in desire or libido, diminished arousal, a decline in the frequency of intercourse, or an undesirable delay or urgency in ejaculation or inability to achieve orgasm.[4] Studies on schizophrenia have revealed that untreated patients have fewer dysfunctions compared to those on antipsychotic medication.[5] Antipsychotic induced sexual dysfunction is said to be related to the effects of the drugs on α1 and α2 adrenergic, H1 histamine and dopaminergic receptors, in particular to the blockade of D2 receptors in pituitary lactotroph cells, which leads to an excess of prolactin secretion.[6] Risperidone has been reported to be having a high frequency of sexual dysfunction and it affects all aspects of sexual function including desire, arousal/erection and orgasm/ejaculation. Risperidone causes sexual dysfunction in approximately 60-70% patients, particulary erectile dysfunction in men, menstrual irregularities, amenorrhea, decreased vaginal lubrication in women; decreased libido and orgasm in both sexes.[4,7,8] The newer SGAs are claimed to be relatively benign with respect to side effects. There are case reports of ejaculatory dysfunction, priapism and galactorrhoea with Iloperidone.[9,10,11] The authors did not come across original articles and reviews on sexual dysfunction with Iloperidone. Amisulpride is known to frequently elevate prolactin levels and hence is associated with sexual side effects.[12,13] One 6 week multicenter, double blind trial comparing safety of Amisulpride with haloperidol reported only one case of impotence in the Haloperidol group compared to no sexual dysfunction in Amisulpride group.[14] Risperidone is a time tested efficacious molecule in the treatment of psychotic disorders, though having significant side effects even in the acute phase treatment.[15] The other two agents are said to be relatively safer, but there is no head to head comparison of these medication for short term sexual side effects in Indian population. This study aims to compare the sexual side effects of widely used risperidone to the newer SGAs Iloperidone and Amisulpride in the acute phase treatment of 6 weeks duration.

METHODS

The project was approved by the institutional ethics committee. This is a 6 week prospective randomized comparative study wherein we assessed the sexual side effects of patients with psychosis, who were administered a monotherapy with Risperidone, Iloperidone or Amisulpride. This study was conducted according to the International Conference on Harmonisation - World Health Organization Good Clinical Practice (ICHGCP) guidelines. It was conducted in the department of psychiatry of a tertiary care teaching hospital at Mysuru, India. The informed consent process was done by the authors, in which the subjects were explained in their language about the purpose of study and its benefits to them, possible adverse effects as well as their autonomy to come off the study whenever they wish. Then, written consent was taken on the consent form before recruiting the subjects. The patient enrolment was done for eight months, from Mar 2015 to Oct 2015. The last visit of the last patient was completed on 25th Nov 2015. Patients having met the criteria for a psychotic disorder according to ICD 10 and consenting to participate in the study were recruited. Both male and female patients in the age range of 18-60 yrs were included. Those with a known history of poor compliance to treatment, those with severe psychopathology and poor insight affecting their ability to understand the study, those with severe medical or psychiatric co-morbid disorders, those with pre-existing sexual dysfunction and pregnant/lactating women were excluded. The medication was administered as per the allocation by computerized randomization. The dose range as per the protocol was 4 to 12 mg for Risperidone, 6 to 18 mg for Iloperidone and 400 to 800 mg of Amisulpride. No concomitant medication like Benzodiazepines was allowed during the study period of 6 weeks. Anticholinergic medication was allowed to be used intermittently but if it was needed as a regular medication, such patients would be dropped. However those who were already taking medication for comorbid stable medical disorders and were not having pre-existing sexual dysfunction were asked to continue same treatment. The study involved three visits. After the initial visit of enrolment into the project, second visit was after three weeks (21 days) and final visit was after 6 weeks (42 days); with a range of ± 2 days for each visit. The randomization was done using computer generated random number tables. Sample size was calculated considering prevalence of psychosis in the general population to be 3.1%. 1 Level of significance 5% and

effect size 8%. The formula we used for calculating sample size is as follows:

$$n = \frac{Z^2 p q}{d^2}$$

Where n = sample size.
Z = appropriate value from the normal distribution for the desired confidence (In this study, the value of Z is taken as 1.96 for 95 % level of confidence).
p = estimated prevalence of schizophrenia.
q = 1-p
d = desired precision (taken as 8 % in this study).
Total sample size was 60, divided into 3 groups of 20 each.
Group 1 consisted of subjects receiving Risperidone.
Group 2 consisted of subjects receiving Iloperidone.
Group 3 consisted of subjects receiving Amisulpride.
Risperidone was started as 2 mg for the first 2 days. Then increased by 1 mg every day upto 6 mg on day 6, which was then continued till week 3. However if there was any adverse event, the subjects were asked to contact the study team to have an interim visit to see if they can be continued further in the study with a dosage change. Also there was a scope to increase the dose further to ≥ 8 mg on week 3 visit (21 days) if the study psychiatrist assessed and found that further increase is essential in view of psychopathology. Similarly, Iloperidone was titrated from 1 mg on day 1, 2 mg on day 2, subsequent increments at 2 mg every day, upto 12 mg on day 7. This dose was continued till week 3 visit, with the option of interim visit as mentioned above. Amisulpride was started as 100 mg on day 1, increased by 100 mg every day till it reached 400 mg on day 4, which would be the minimum effective dose to be continued till week 3 visit unless it needed further interim assessment. Among the 94 subjects screened and interviewed, a total of 65 were enrolled into the study. Sixty subjects completed all the three study visits. Two subjects on Iloperidone were lost to follow up, two on Risperidone and one on Amisulpride were discontinued as they developed severe EPS. Among the completed subjects, 45 were diagnosed as schizophrenia- first episode or relapse, but were not on treatment for at least past 2 months. Twelve were diagnosed to have acute and transient psychotic disorder (ATPD) and 3 were having unspecified non-organic psychosis, who were drug naive. The symptomatic improvement during visits was assessed based on unstructured but detailed clinical interview by the study psychiatrists. Then the sexual dysfunction was assessed using UKU side effect rating scale.16 All assessments of a particular patient were completed on a single day and the allotted medication started the same day. We did not undertake any blood investigations like serum prolactin levels. Clinical improvement in psychopathology was assessed during all visits with clinical interview. The statistical analysis was done using descriptive statistics for socio-demographic and clinical variables. Frequency distribution of side effects in UKU side effect rating scale was analysed using Cramer's V test. P values < 0.05 were considered statistically significant.

RESULTS

This is a prospective randomized comparative study involving 3 visits. We compared the socio demographic variables and the items of sexual function on UKU side effect rating scale of study population who were administered – Risperidone, Iloperidone and Amisulpride. There was no significant difference across the three groups for age and sex. The mean age for Risperidone group was 35.05±9.71 yrs, for Iloperidone group it was 29.75±8.14 yrs and for Amisulpride group it was 32.53±8.90 yrs. In the Risperidone group there were 11 males and 9 females. The Iloperidone and Amisulpride groups had 10 males and females each. The table 1 shows that the other socio-demographic variables of the three groups are comparable. The table 2 shows the mean doses of the study medication. On the UKU side effect rating scale, at base line no subjects reported sexual side effects on the UKU side effect rating scale. At week 3, 3 on Risperidone, 9 on Iloperidone and 1 on Amisulpride reported increase in sexual desire, all rated at score 1 on the scale. Also one subject on Iloperidone reported diminished sexual desire. At the end of 6 weeks, 15% (n=3) of subjects on Risperidone and 20% on Iloperidone (n=4) reported sexual dysfunction in the area of desire. None on Amisulpride reported any sexual dysfunction at the end of 6 weeks. Details are shown in table 4. At week 6, Out of the 3 subjects in Risperidone group, 2 reported decreased sexual desire and one reported increased sexual desire. In Iloperidone group, 3 reported increased sexual desire and one decreased sexual desire. The table 3 shows the change in mean scores across the study visits. There is a significant change in the mean scores for increased desire (p=0.05), within the Iloperidone group, from visit 2 to visit 3, implicating iloperidone to be associated with significant increased desire at week 3 (visit 2). But the number reporting this decreased from 9 in visit 2 to 3 in visit 3, thus showing improvement in that side effect. However as shown in the table 3, the frequency of sexual side effects did not show significant difference across the groups for increased sexual desire, though it was relatively higher for iloperidone. Further the severity score on the UKU scale of all subjects in all visits was 1 (except the subject on Iloperidone, where it progressed from 1 to 2 ie moderate level, by week 6), indicating mild dysfunction. None of the women reported amenorrhoea or galactorrhoea during the study period of 6 weeks. Further,

at the end of the study, increased sexual desire was reported by one woman on iloperidone, rest of the three were men (2 on Iloperidone and 1 on Risperidone). Diminished sexual desire was reported by two women, one on iloperidone and one on Risperidone. One man on Risperidone also reported diminished desire. Further there was no difficulty expressed in arousal/erection and orgasm/ejaculation in both sexes. Overall the results are favourable for all the three medication for the development of sexual side effects during the short duration treatment of 6 weeks, as not many patients reported sexual side effects in our study.

Table 1: Socio-demographic distribution

Characteristics	Group I (R)	Group II (I)	Group III (A)	p
Age (in yrs)				
8-30	8 (40%)	12 (60%)	9 (45%)	0.169
31-60	12 (60%)	8 (40%)	11 (55%)	
Sex				
Male	9 (45%)	10 (50%)	10 (50%)	0.935
Female	11 (55%)	10 (50%)	10 (50%)	
Education				
Illiterate	10 (50%)	7 (35%)	8 (40%)	
upto 9	3 (15%)	4 (20%)	3 (15%)	
SSLC	6 (30%)	4 (20%)	4 (20%)	0.749
PUC	1 (5%)	3 (15%)	4 (20%)	
Degree/Diploma	0	2 (10%)	1 (5%)	
Occupation				
Home maker	5 (25%)	6 (30%)	5 (25%0	
Agriculture	8 (40%)	4 (20%)	5 (25%)	
Business	2 (10%)	2 (10%)	3 (15%)	
Daily wage	5 (25%)	6 (30%)	6 (30%)	0.887
Student	0	1 (5%)	1 (5%)	
Unemployed	0	1 (5%)	0	
Family type				
Nuclear	14 (70%)	15 (75%)	14 (70%)	0.921
Extended	6 (30%)	5 (25%)	6 (30%)	
Marital status				
Single	5 (25%)	7 (35%)	5 (25%)	0.720
Married	15 (75%)	13 (65%)	15 (75%)	
Domicile				
Rural	14 (70%)	15 (75%)	13 (65%)	
Sub urban	4 (20%)	4 (20%)	6 (30%)	0.876
Urban	2 (10%)	1 (5%)	1 (5%)	

Table 2: Mean dose of the study drugs in 'mg' across all the visits

Study drugs	Visit 1 Mean ± SD	Visit 2 Mean ± SD	Visit 3 Mean ± SD
Risperidone	5.30 ± 1.75	5.00 ± 1.65	4.60 ± 1.39
Iloperidone	9.00 ± 2.79	7.80 ± 2.14	7.40 ± 2.01
Amisulpride	380±50.50	350±25.26	356±56.12

Table 3: Change in mean scores of sexual side effects among the study subjects. (UKU Side Effect Rating Scale)

	Group I (Risperidone)		Group II (Iloperidone)		Group III (Amisulpride)		P
Visits	3 weeks	6 weeks	3 weeks	6 weeks	3 weeks	6 weeks	
Increased desire	0.15±0.36	0.05±0.2	0.6±0.75	0.25±0.63	0.1±0.44	0	0.05
Decreased desire	0	0.1±0.3	0.5±0.22	0.15±0.42	0	0	0.145

***p < 0.05 is statistically significant**

Table 4: Frequency distribution of Sexual Dysfunction in the study subjects

	Group 1 (Risperidone)		Group 2 (Iloperidone)		Group 3 (Amisulpride)		Cramer's V test
VISITS	3 weeks	6 weeks	3 weeks	6 weeks	3 weeks	6 weeks	p
Increased desire	3(15%)	1(5%)	9(45%)	3(15%)	1(5%)	0	0.06
Decreased desire	0	2(10%)	1(5%)	1(5%)	0	0	0.349

*p < 0.05 is statistically significant

DISCUSSION

This is a prospective randomized comparative study wherein we compared the gold standard Risperidone with the newer SGAs Iloperidone and Amisulpride for sexual adverse effects. The initial experience with an antipsychotic is important for long term compliance. The sexual side effects are perceived by patients to be humiliating and demoralizing in their relationships. Though it can be a significant issue in the long term, changes can be noticed as early as 4 weeks. The newer SGAs have been reported to be relatively safer as far as sexual side effects are concerned. Our objective is to look into the early onset sexual side effects with the newer agents Iloperidone and Amisulpride and to compare it with the gold standard atypical antipsychotic Risperidone. Several studies and clinical trials have shown that Risperidone consistently causes a high degree of sexual dysfunction.[4,7,8,17] Most studies relate it to hyperprolactinemia. In our study, though we did not include prolactin estimation, patients on Risperidone reported sexual side effects as early as 3 weeks and by the end of 6 weeks 15% reported sexual dysfunction. A lower rate of reported sexual dysfunction in our study could be probably due to the shorter duration of treatment when it was assessed. With Amisulpride, the studies are equivocal. Some studies report a very low sexual side effects, as low as 1%.[14, 18] Some other studies report a high frequency of sexual dysfunction. In one study it was as high as 65% at 6 weeks, as assessed by UKU side effects rating scale. However pre-treatment sexual dysfunction was as high as 68% in this study and hence the difference is actually favourable for Amisulpride.[19] In our study, one subject with a diagnosis of schizophrenia, on Amisulpride reported increased desire on UKU side effect rating scale at the end of 3 weeks, that was not seen at the end of 6 weeks. Thus none of them on Amisulpride reported any sexual side effects at the end of 6 weeks. This supports the earlier 6 week multicenter, double blind trial comparing safety of Amisulpride with haloperidol which reported a very low incidence of sexual side effects. It reported only one case of impotence in the Haloperidol group compared to no sexual dysfunction in Amisulpride group.[14] With Iloperidone, 9 subjects in our study reported increased sexual desire at the end of 3 weeks. However at the end of 6 weeks, only 3 of them persisted with this complaint and it had resolved in six others. No subjects reported other sexual dysfunction such as erectile dysfunction or orgasmic problems. There is a case series that reported 5 subjects on Iloperidone having retrograde ejaculation.[9] Another case report reported priapism.[10] These effects are attributed to Alpha-1 adrenergic antagonistic property of Iloperidone. There is another report of galactorrhoea and amenorrhoea due to hyperprolactinemia that developed after 3 months of treatment with 8 mg of Iloperidone.[11] The authors did not come across any large scale prevalence studies/original articles on sexual dysfunction with Iloperidone. However, the interesting finding in our study is that Iloperidone was associated with a comparatively higher frequency of sexual side effects (20%), affecting only the desire component, in contrast to other studies. It is important to interpret the meaning of increased sexual desire in this study. A total of 13 (9 in Iloperidone group) out of 60 subjects reported this at the end of 3 weeks. This however reduced by more than 50%, to 4 (3 in Iloperidone group) out of 60 at 6 weeks. This would also explain the intragroup significant difference in mean score for increased desire in Iloperidone group. None of these 13 subjects had any affective/manic symptoms at base line, nor they showed any mood symptoms following treatment, which could otherwise be interpreted as the reason for increased sexual desire. All of them were scored 1 on this item. A score of 1 on the UKU scale for increased sexual desire means there is slight increase, which is, however, still felt as natural by the partner. Though it is relevant to report this as a side effect on UKU scale, this increase in sexual desire could possibly be a sign of clinical improvement in psychopathology as a response to treatment. Once they started showing improvement, with better level of functioning, their interpretation of sexual functioning could have been perceived as increased. By another 3 weeks, most of them did not perceive it as increased desire. This is possibly due to the gradual onset of the effect of the antipsychotic drugs on receptors/hormones affecting sexual functioning. Going by this, continuation of the study beyond six weeks would have possibly identified more subjects reporting sexual side effects. This is the authors interpretation of this finding. However the authors have come across case reports of hypersexuality with SGAs such as Risperidone, Clozapine, Olanzapine, Aripiprazole

and Paliperidone in pubmed search, but not with Iloperidone and Amisulpride. Also, a 2011 article inferred that sexual dysfunction became better when subjects were assessed 12 weeks after switching from FGAs to SGAs that comprised Risperidone, Amisulpride, Olanzapine and Quetiapine. [20] Thus it is possible that sexual dysfunction may improve in some people with improvement in psychopathology. All in all, in this study, sexual dysfunction is recorded less frequently with SGAs compared to similar such studies in the past which reported higher dysfunction with Risperidone and Amisulpride, [8,17,19] though results with Amisulpride are equivocal as mentioned above. An important factor that influences the results in such studies is the dose of study drugs. In our study, there was a mild reduction of dosage by the end of the study owing to reasons such as weight gain and EPS. The dose of Risperidone was in the range of 4 to 6 mg across visits 2 and 3, Iloperidone dose varied from 7.5 to 9 mg and Amisulpride 300-500 mg. The doses equivalent to 100 mg/day of chlorpromazine is 2mg/day for Risperidone and 6mg/day for Iloperidone.[21,22] There was no reliable reference for equivalent dose of Amisulpride available to authors for a statistical comparison. The chlorpromazine equivalent dose, however, for Risperidone was evidently higher compared to Iloperidone in this study. Yet there was no significant difference in the sexual side effects between the study drugs. This is a randomized prospective study, a design most suited for such comparative studies. Though attrition rate is sometimes a major drawback in such designs, it was about 8% in this study with 60 out of 65 subjects completing the study having three visits, on day 1, 21 and 42. However, though ours is a randomized study, we did not randomize the doses of the study medication. Further, it was not a placebo controlled study, owing to the ethical issues of the institutional ethics committee. We consider that our sample size is not sufficient enough for generalization of our findings. Also our study is of shorter duration and more sexual side effects have been reported longer into the treatment, in previous studies.

CONCLUSION

Our study shows that Risperidone, Iloperidone and Amisulpride are comparable for the frequency and severity of sexual side effects over 6 weeks of acute phase treatment. Though more subjects on Iloperidone reported increased sexual desire initially into the study, it was mild and reduced significantly by the end of the study. Long term studies with a larger sample size and matched chlorpromazine equivalent doses may be needed to generalize our result. All in all, Iloperidone, though appears relatively safer with respect to sexual side effects from the literature, our study revealed that it needs to be used cautiously with respect to sexual safety, even in short term.

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