

POST MARKETING SURVEILLANCE STUDY ON RISPERIDONE IN PATIENTS SUFFERING FROM SCHIZOPHRENIA

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ABSTRACT

Schizophrenia is one of the commonest psychiatric ailments. It has been estimated that approximately 1% of the population and 15% of the adults suffers from this disease.

Risperidone, atypical antipsychotic, acts mainly by 5HT₂ blockade action. Produce virtually no extra pyramidal side effects at low dose, has a broad efficacy. But extra pyramidal dysfunction can appear at higher doses.

We conducted a post marketing surveillance study on risperidone in 40 patients suffering from schizophrenia at Psychiatric department of Civil Hospital, Ahmedabad. In this study we specially studied its efficacy and safety.

The results of this study are consistent with phase III clinical studies on risperidone carried out in Indian patients except its effects on food intake.

As far as the efficacy of risperidone in patient with schizophrenia is concerned, it provided good symptomatic relief

In term of safety, 7 patients out of 40, experience adverse effects like decrease appetite, constipation, insomnia, EPS and NMS. Patient with NMS was admitted in hospital and was died later on.

Keywords: Post Marketing Surveillance, Risperidone, Schizophrenia

INTRODUCTION

Schizophrenia is one of the commonest psychiatric ailments with about 1% of the population and 15% of the adults suffers from this disease.

Schizophrenia affects about 24 million people worldwide.

They developed positive symptoms like auditory and visual hallucinations, strong or inappropriate emotions and negative symptoms like loss of interest in surroundings mainly due to dopaminergic hyperactivity. It usually starts early in the life and is a chronic disorder with a strong hereditary basis.

Risperidone is a novel serotonin-dopamine antagonist, atypical antipsychotic drug in a class of benzisoxazole derivative, acts mainly by 5HT₂ blockade action, being used with increasing frequency throughout the world. Its unique properties make it a promising but challenging drug to use in the treatment of schizophrenia. Produce virtually no extra pyramidal

side effects at low dose, has a broad efficacy. But extra pyramidal dysfunction can appear at higher doses.

When treating the symptoms of schizophrenia (such as hallucinations or delusions), it usually takes 3 - 6 weeks or longer before the benefits of risperidone are noticeable.

When Risperidone is working well for those with schizophrenia, some people notice that their thoughts are clearer and more organized.

Risperidone may help control your symptoms but will not cure your condition. It may take several weeks or longer before you feel the full benefit of risperidone. Continue to take risperidone even if you feel well.

With this background, we conducted post marketing surveillance study on risperidone in 40 patients suffering from schizophrenia at Psychiatric department of Civil Hospital, Ahmedabad. In this study we specially studied its efficacy and safety.

MATERIALS AND METHODS

Study population

The study population consisted of 40 patients, both newly diagnosed and patients already suffering from schizophrenia. Patients enrolled into the study, as per the inclusion and exclusion criteria defined in the protocol, formed the study population

Patient enrollment

The investigator, according to the inclusion and exclusion criteria and the willingness of the individual patient, enrolled 40 patients in the study at Psychiatric department of Civil Hospital, Ahmedabad.

Study protocol

This was an open study in schizophrenic patients. Both newly diagnosed and patients already suffering from schizophrenia were enrolled in the study. The treatment duration of study was 8 weeks. The safety of risperidone was evaluated by monitoring the patient's health. Patients were observed for adverse events. The efficacy was evaluated based on symptomatic relief.

Medications

The patients received risperidone 1 mg to 4 mg per tablet. Risperidone was given 1 mg BD and in some cases followed by increase of 1 mg twice daily to a target dose of 3 mg BD by third day. At one time, patients received only 1 week's medication and had to revert to the investigator for a refill of the medication, every week.

As much as possible no concomitant medication was allowed.

OBSERVATIONS AND RESULTS

During our study we reported 7 patients out of 40, experience adverse effects. 3 patients complaining that food intake was reduced. 1 patient having constipation. 1 patient having insomnia. 1 patient stopped risperidone because of extra pyramidal symptoms after 14 days of starting risperidone. 1 patient having altered behavior, irrelevant talking and some other sign and symptoms, so that physician, were suspecting neuroleptic malignant syndrome. 2 patients (NMS & EPS) were advised to stop taking risperidone. 1 patient stopped because of poor compliance but after 1 month, he restarted the risperidone. Patient with NMS was admitted in hospital and was died later on.

OTHER RESULTS

1) In 37 cases compliance was very good.

- 2) In 2 cases rebound psychosis were seen when they stop the risperidone.
- 3) 2 patients were taking haloperidole but due to adverse effects and less efficacy they were started risperidone and they respond well to risperidone
- 4) Other antipsychotic drug like haloperidole was prescribed more as compare to risperidone because of less cost.
- 5) Some physicians avoided the prescribing the risperidone due to some bias.

DISCUSSION AND CONCLUSION

This study was designed to evaluate effect of risperidone on food intake in patients, to compare and support results of our main study that was "Effect Of Risperidone On Food Intake In Experimental Animals (Albino Rats) And Its Post Marketing Surveillance".

In order to use Risperidone most effectively and efficiently; clinicians must be aware of its potential benefits and risks. This report is a review and critical evaluation of current knowledge regarding the clinical efficacy and side effects of Risperidone. Although risperidone has proven to be effective in some refractory schizophrenic patients and to produce relatively few extrapyramidal side effect compare to classical neuroleptic drugs, several issues require further investigation (research) including what defines neuroleptic intolerance, the optimal dose range and the appropriate duration of a risperidone treatment trial. This report is intended to provide an overview of current knowledge of clinical effects of risperidone, both therapeutic and adverse. This is a rapidly evolving area of investigation but numerous questions remain unanswered.

Many of the side effects that have been observed with risperidone could be predicted from its pharmacological properties. Side effects other than established in phase III could not have been predicted or observed until risperidone was administered to large number of patients for extended period of time. In our study 3 patients having reduced appetite during risperidone treatment, which is unestablished side effect, this results is in support our main study about hypophagic effect of risperidone on albino rats.

The most common reasons for discontinuation were failure to achieve a therapeutic effect, non compliance and adverse side effect. One important reason given for neuroleptic medication non compliance is the occurrence of EPS particularly akathisia.

In our study 2 reports of rapid returns of psychotic symptoms after abrupt discontinuation of risperidone which can be because of super sensitivity of mesolimbic system.

Risperidone is an antipsychotic with the benefit of "No Weight Gain" during long duration effect and hence the obesity related complication can be obviated.

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