Piracetam in Alcoholic Psychoses: A Double-Blind, Crossover, Placebo Controlled Study

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Journal of International Medical Research 1985 13: 185
DOI: 10.1177/030006058501300307

J Int Med Res (1985) **13**, 185

Piracetam in Alcoholic Psychoses: A Double-Blind, Crossover, Placebo Controlled Study

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Introduction

Various therapeutic approaches are applied for the treatment of psychiatric complications in patients suffering from chronic alcoholism, such as in the case of predelirium state, in delirium tremens and in alcoholic hallucinosis.

One aim is to normalize the basic metabolic functions by means of the administration of infusions containing minerals, vitamins and glucose in order to rehydrate the patient, the other aim is a purely symptomatic treatment using tranquillizers and neuroleptics.

Piracetam, a nootrop, may offer another rationale for therapy as it directly activates the higher cortical functions of the brain such as those involved with cognition, memory formation and retrieval, thought and state of consciousness and in the case of toxic aggression it facilitates restoration of normal brain activity.

Piracetam has previously been studied in patients presenting with alcoholic psychosis in several open trials involving a total of about 200 patients (Aron & Nerot 1975, De Buck *et al* 1970, Delooz 1979, Marx 1974, Meyer *et al* 1979, Pottier 1973, Turon *et al* 1971).

Our aim was to confirm the therapeutic properties of piracetam in alcoholic psychoses mentioned in the open trials by means of a double-blind, crossover study using placebo as the control agent.

Method

Twenty-four male patients with a mean age of 36·7 years (range 24–54 years) were included. All of them were diagnosed as presenting with an alcoholic psychosis, i.e. sixteen patients had a predelirium or delirium state and eight patients had an alcoholic hallucinosis. They were randomly allocated into two groups.

Psychopathological characteristics of the patients were studied at the start and during the course of the study using the Brief Psychiatric Rating Scale (BPRS) of Overall and Gorham (1962). The test during the study was performed every evening by the attending physician under double-blind conditions.

One group of twelve patients with the following characteristics, mean age 37·4 years (range 26–54 years), initial BPRS scores in the range of 36–55 with a mean of 46·42, were treated with piracetam (Nootropil) given by the intravenous route with a daily dosage of 9 g (3 g t.i.d.) over a period of 3 days. This active treatment was followed by 3 days of administration of identically appearing placebo.

The second group of twelve patients with the following characteristics, mean age 35·9 years (range 25–54 years), initial BPRS scores 38–52 with a mean of 45·75, was given the reverse sequence, 3 days of placebo followed by 3 days of 9 g piracetam daily.

Standard treatment with infusions containing glucose, minerals and vitamins was given to all patients. Volume (to a maximum of 2,000 ml) was given in accordance with the clinical picture.

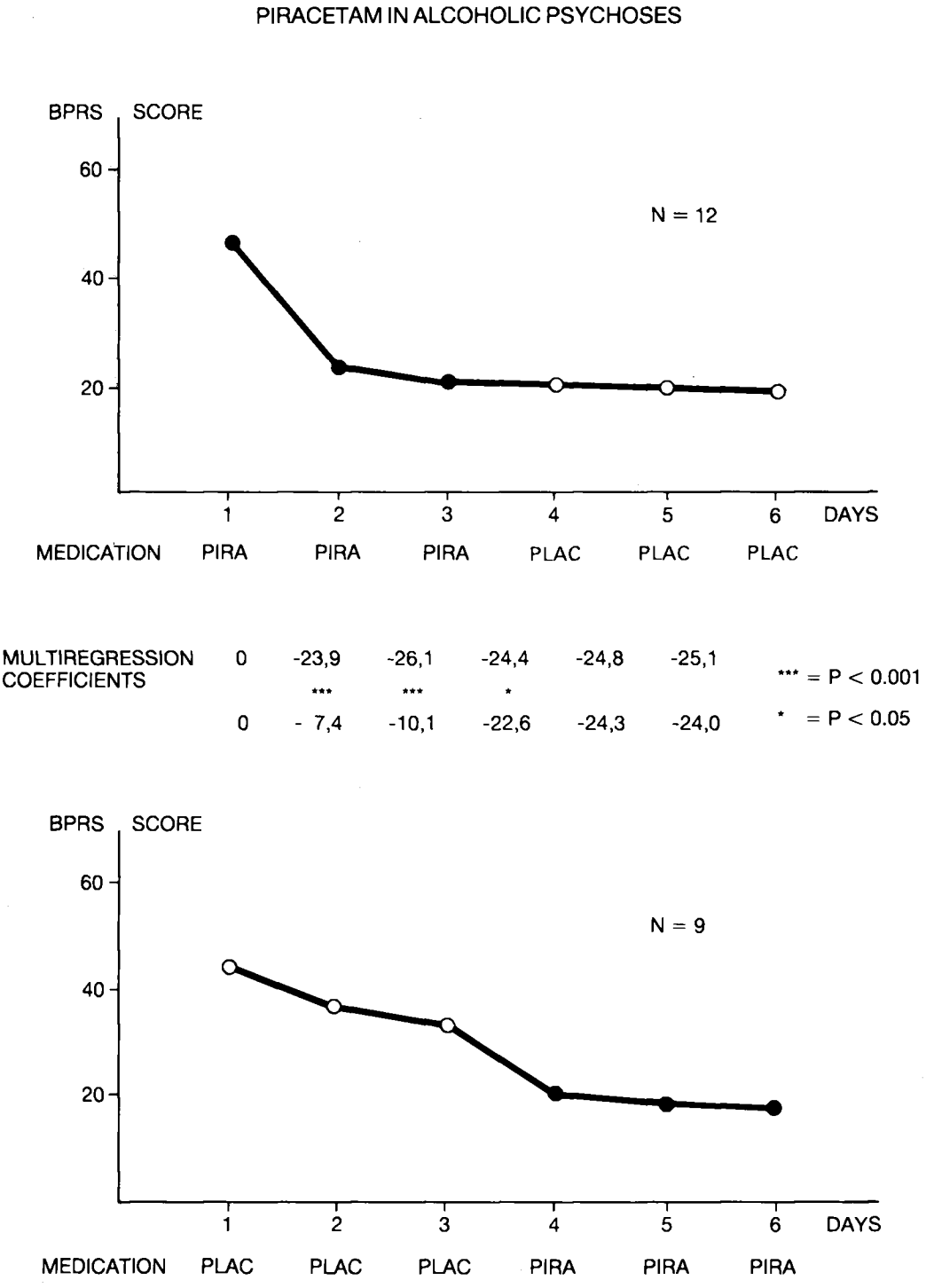

Fig 1 *Piracetam versus placebo in alcoholic psychosis*

For ethical reasons, repeated administration of diazepam 20 mg was allowed in cases presenting with serious restlessness due to the psychotic state. No other treatment was allowed.

Results

The data from the patients who completed the trial were statistically evaluated by multi-regression analysis. The results are graphically shown in Figure 1.

With the t test, the means observed in group A and group B have been compared in order to see if the order of administration of active drug or placebo influenced the results. This difference is highly significant with $p = 0{\cdot}001$.

Clinical improvement could be observed in both groups but a statistically significantly better effect was to be seen in the group first treated with piracetam. The clinical improvement observed during the initial treatment with piracetam was carried over after crossing over to the placebo period. The slight clinical improvement observed in the group first treated with placebo was markedly improved after crossing over to piracetam on the 4th day. No differences could be shown during the last 2 days of the study.

There were no adverse reactions noted in patients on piracetam.

It is interesting to note that all three drop-outs occurred in the group starting on placebo. Two of them because of the necessity for neuroleptic treatment and one because of a suicide attempt.

It is also interesting to note that seven patients in the group who were administered placebo first had to be given diazepam during the placebo period. Only one patient receiving piracetam as initial treatment required diazepam.

Discussion

The results observed in this double-blind, crossover trial confirm the evidence of the favourable effect of piracetam in alcoholic psychoses gathered in open trials.

For ethical reasons, administration of diazepam was allowed as a symptomatic treatment. This had to be given in seven out of the twelve patients receiving placebo during the first 3 days and in one patient given piracetam during the first 3 days.

This may have interfered to some extent with the evaluation during the first period but on the other hand it suggests a favourable effect of piracetam. In this study piracetam proved to be a useful and well tolerated agent in the treatment of alcoholic psychosis.

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