Editorial

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Drop outs in a trial on functional dyspepsia

Abstract

Clinical studies on functional diseases have a high rate of placebo response and drop outs. This study aimed at the identification of some possible factors related to drop outs in a functional dyspepsia clinical trial. Type of treatment, sex and age were not associated with dropouts, whereas the use of rescue medication during the trail and the distance from home to the outpatient clinic showed an statistically significant association.

Keywords: dyspepsia, patient dropout

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Editorial

Clinical studies on functional diseases have a high rate of placebo response and withdrawal of participants. Among the common causes of drop out are inconvenience to the study, scheduling conflicts, personal and financial problems, fear, anxiety, lack of observable improvement of symptoms, drug side effects, among others. It is well known that, in controlled therapeutic trials, responses to placebo occurs in a high percentage of patients with functional dyspepsia. This indicates that, in addition to the active principle of the drug employed, other factors seem to influence the success of the treatment. These include proper guidance on the nature of the disease, reassurance about the benignity of this clinical condition, ensuring access to medical care when needed and, above all, trusting the physician. We studied some factors related to loss of follow-up among participants of a clinical study on functional dyspepsia. We conducted a randomized double-blind clinical study on functional dyspepsia at the Gastroenterology Department of Faculdade de Medicina do ABC, in Brazil. The study involved 114 patients followed up for 6months, who underwent different interventions: omeprazole or placebo (unpublished data). From this study, a subset of data referring to patients who dropped out was obtained. We analyzed age, sex, treatment, distance from the home to the place of care, use of antacid as a rescue medication and intensity of symptoms upon entering the study. This last parameter was evaluated by the Porto Alegre Questionnaire for Functional Dyspepsia, a questionnaire developed and validated in Brazil for this purpose . One hundred fourteen patients were enrolled, of whom 55 did not finish the study. Among these, there was no significant association between the type of therapy used and the dropout (p=0.51 chi-square test), as well as between sex (p=0.07- Fisher exact test), age group (up to Chi-square test), and the score of the Porto Alegre questionnaire when entering the study (p=0.43- chi-square test). Drop outs were associated with the distance between home and the outpatient clinic (p=0.002 chi-square test). Between the participants inhabitants up to 5km away, there were 72% of abandonment, inhabitants up to 10km 40% of abandonment, and 42.8% for inhabitants more than 10km away. Drop out was also associated with the use of rescue medication: 17.3% of patients who used an antacid on average once or twice a day, and 18% of those who used 2 to 3times a day abandoned the study , but among those who did not used rescue antacid the dropout was 91%. The combined analysis of the two significant variables shows that among patients who did not finish the study and live up to 5 km from the outpatient clinic, 83.3% did not use rescue medication, among inhabitants up to 10 km 73% did not use, and inhabitants more than 10km 72.2% did not use rescue medication. Among the patients who completed the study, residents up to 5km all took rescue antacids, among those living up to 10km 92.5% used, and more than 10km 87.5% took rescue antacids. In conclusion, for this group of Brazilian patients the drop out rate was not related to the patient's age, gender or type of treatment, whereas proceeding until the end of the study was strongly associated with the use of rescue medication, being the distance from the outpatient clinic up to home a confounding variable.

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Conflicts of interest

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