Statistical Issues in Pharmacoepidemiological Case-control Studies

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Abstract

Pharmacoepidemiology is the study of the use and the effect of drugs in large numbers of people. The work relies largely on standard epidemiological principles, which, applied in a new context, bring particular constraints and opportunities.

In January 1994, a cluster of children with cystic fibrosis (CF) who developed strictures in the colon was reported. It was suggested that these may have been associated with high strength pancreatic enzyme preparations which had been introduced into use in these patients approximately one year previously. This hypothesis has been evaluated by a case-control study which confirms the association with high-strength pancreatic enzyme usage.

The study is described and is used to illustrate statistical issues to provide a framework for future research in statistical methodology in pharmacoepidemiological case-control studies.