16. Main results:

16 (a). Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence intervals). Make clear which confounders

were adjusted for and why they were included.

Example 1 ‘‘We initially considered the following variables as potential confounders by Mantel-Haenszel stratified analysis: (...) The variables we included in the final logistic regression models were those (...) that produced a 10% change in the odds ratio after the Mantel-Haenszel adjustment’’.

Explanation

In many situations, authors may present the results of unadjusted or minimally adjusted analyses and those from fully adjusted analyses. We advise giving the unadjusted analyses together with the main data, for example the number of cases and controls that were exposed or not. This allows the reader to understand the data behind the measures of association (see also item 15). For adjusted analyses, report the number of persons in the analysis, as this number may differ because of missing values in covariates (see also item 12c). Estimates should be given with confidence intervals. Readers can compare unadjusted measures of association with those adjusted for potential confounders and judge by how much, and in what direction, they changed. Readers may think that ‘adjusted’ results equal the causal part of the measure of association, but adjusted results are not necessarily free of random sampling error, selection bias, information bias, or residual confounding (see Box 5). Thus, great care should be exercised when interpreting adjusted results, as the validity of results often depends crucially on complete knowledge of important confounders, their precise measurement, and appropriate specification in the statistical model (see also item 20). Authors should explain all potential confounders considered, and the criteria for excluding or including variables in statistical models. Decisions about excluding or including variables should be guided by knowledge, or explicit assumptions, on causal relations. Inappropriate decisions may introduce bias, for example by including variables that are in the causal pathway between exposure and disease (unless the aim is to asses how much of the effect is carried by the intermediary variable). If the decision to include a variable in the model was based on the change in the estimate, it is important to report what change was considered sufficiently important to justify its inclusion. If a ‘backward deletion’ or ‘forward inclusion’ strategy was used to select confounders, explain that process and give the significance level for rejecting the null hypothesis of no confounding. Of note, we and others do not advise selecting confounders based solely on statistical significance testing. Recent studies of the quality of reporting of epidemiological studies found that confidence intervals were reported in most articles . However, few authors explained their choice of confounding variables.

(b). Report category boundaries when continuous variables were categorised.

Example Table

Explanation

Categorizing continuous data has several important implications for analysis (see Box 4) and also affects the presentation of results. In tables, outcomes should be given for each exposure category, for example as counts of persons at risk, person-time at risk, if relevant separately for each group (e.g., cases and controls). Details of the categories used may aid comparison of studies and meta-analysis. If data were grouped using conventional cut-points, such as body mass index thresholds, group boundaries (i.e., range of values) can be derived easily, except for the highest and lowest categories. If quantile-derived categories are used, the category boundaries cannot be inferred from the data. As a minimum, authors should report the category boundaries; it is helpful also to report the range of the data and the mean or median values within categories.

(c). If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.

Example ‘‘10 years’ use of HRT [hormone replacement therapy] is estimated to result in five (95% CI 3–7) additional breast cancers per 1000 users of oestrogen-only preparations and 19 (15–23) additional cancers per 1000 users of oestrogenprogestagen combinations’’.

Explanation

The results from studies examining the association between an exposure and a disease are commonly reported in relative terms, as ratios of risks, rates or odds (see Box 8). Relative measures capture the strength of the association between an exposure and disease. If the relative risk is a long way from 1 it is less likely that the association is due to confounding.

Relative effects or associations tend to be more consistent across studies and populations than absolute measures, but what often tends to be the case may be irrelevant in a particular instance. For example, similar relative risks were obtained for the classic cardiovascular risk factors for men living in Northern Ireland, France, the USA and Germany, despite the fact that the underlying risk of coronary heart disease varies substantially between these countries. In contrast, in a study of hypertension as a risk factor for cardiovascular disease mortality, the data were more compatible with a constant rate difference than with a constant rate ratio. Widely used statistical models, including logistic and proportional hazards (Cox) regression are based on ratio measures. In these models, only departures from constancy of ratio effect measures are easily discerned. Nevertheless, measures which assess departures from additivity of risk differences, such as the Relative Excess Risk from Interaction (RERI, see item 12b and Box 8), can be estimated in models based on ratio measures. In many circumstances, the absolute risk associated with an exposure is of greater interest than the relative risk. For example, if the focus is on adverse effects of a drug, one will want to know the number of additional cases per unit time of use (e.g., days, weeks, or years). The example gives the additional number of breast cancer cases per 1000 women who used hormone-replacement therapy for 10 years. Measures such as the attributable risk or population attributable fraction may be useful to gauge how much disease can be prevented if the exposure is eliminated. They should preferably be presented together with a measure of statistical uncertainty (e.g., confidence intervals as in the example). Authors should be aware of the strong assumptions made in this context, including a causal relationship between a risk factor and disease (also see Box 7). Because of the semantic ambiguity and complexities involved, authors should report in detail what methods were used to calculate attributable risks, ideally giving the formulae used. A recent survey of abstracts of 222 articles published in leading medical journals found that in 62% of abstracts of randomised trials including a ratio measure absolute risks were given, but only in 21% of abstracts of cohort studies. A free text search of Medline 1966 to 1997 showed that 619 items mentioned attributable risks in the title or abstract, compared to 18,955 using relative risk or odds ratio, for a ratio of 1 to 31.