Summary points

Composite end points are outcomes that capture the number of patients experiencing one or more of several adverse events

The validity of composite end points depends on similarity in patient importance, treatment effect, and number of events across the components

When large variations exist between components the composite end point should be abandoned

infarction with subsequent disability far more important than a short admission for acute coronary syndrome with rapid return to previous function.

The answers to the other two questions are also negative. Hospital admissions occurred far more frequently than the two more important events (table). Biological rationale fails to support a presumption that the invasive strategy will have similar effects on all three end points. Indeed, the investigators explicitly state that they expect an increase in short term deaths with surgery, while achieving benefits in terms of decreased angina and associated hospital admissions. The trend toward increased deaths, with a large reduction in admissions, with the invasive strategy provides support for this hypothesis. The composite end point thus fails all three criteria and provides little useful information for clinical decision making.

Conclusions

The widespread use of composite end points reflects their elegant simplicity as a solution to the problem of declining event rates. Unfortunately, use of composite end points makes the interpretation of the results of randomised trials for clinical decision making challenging. Investigators and their sponsors may claim treatment effects over a broad range of outcomes, whereas the effect may in fact be limited to one component. Occasionally, composite end points prove useful and informative for clinical decision making. Often, they do not. These users' guides will help clinicians differentiate between these situations.

Contributors and sources: The authors are clinicians, methodologists, and trialists with expertise in the conduct or the interpretation of clinical trials. In preparation for this article we reviewed Medline and the Cochrane Methodology Register for studies, editorials, and commentaries about the use of composite end points in clinical trials. GP-M, IF-G, and GHG conceived the idea for the article; VMM, GP-M, IF-G, and GHG reviewed the methodological literature and contributed to the framework presented in this manuscript; VMM and GHG created the first draft, and edited subsequent revisions; all authors offered critical revisions to the manuscript and the illustrative examples we used in the manuscript; all approved the final version; GHG is the guarantor.

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Corrections and clarifications

Population based randomised controlled trial on impact of screening on mortality from abdominal aortic aneurysm

Tables 2 and 3 of both the abridged and the full versions of this paper by Paul E Norman and colleagues contain some incorrect values (*BMJ* 2004;329:1259-62). In table 2, for the emergency procedures the "all ruptures" values are 19 and 22 for the "not scanned" and "total invited" groups respectively and 27 in the control group; in table 3, the corresponding values are 32, 35, and 38. The authors state, however, that this amendment does not alter their analyses or conclusions.

Risk of ischaemic stroke in people with migraine: systematic review and meta-analysis of observational studies

In our haste to correct this paper by Etminan and colleagues (*BMJ* 2005;330:63-5, 8 Jan), some of the authors' late corrections were not carried out properly—either at proof stage of the abridged print version or in the correction that we subsequently published on the web relating to the full version only. In the abridged version, the relative risk for migraine with aura in table 2 should be 2.88 (not 2.28); in table 1, the upper confidence limit for migraine with aura for Schwaag should be 3.53 (not 3.35), and the cases:controls for the Collaborative Group should be 430:151 (not 430:451). In the results section of the full version, the references for the data on migraine with and without aura are numbers 2, 3, 12-14, 17-19; in table 1, the cases:controls with migraine is 26:26 for Donaghy (not for Chang as stated in the previous correction).

Minerva

The eighth Minerva item (about a study published in *Neurology*) in the issue of 22 January (*BMJ* 2005;330:204) may have misled readers by including as its first sentence: "Survival in patients with Parkinson's disease is less than in the general population." This statement applies generally and is contradictory to the actual finding of the study, which is presented in the rest of the item. We should and could have made it clearer that the first statement was intended, as in most Minerva items, as background.