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Non-inferiority = a non-event!

Among the new drugs examined recently, three clinical dossiers submitted in support of successful marketing applications were based mostly on the results of "non-inferiority" trials.

In the case of bivalirudin, a drug used before some coronary artery interventions, immediately or shortly after acute coronary events, more than 13 000 patients accepted to participate in the clinical trial (French edition September 2008 page 648). Likewise, more than 450 patients consented to receive albumin-bound paclitaxel for metastatic breast cancer (page 8), and more than 200 patients were willing to try anidulafungin for invasive candidiasis (page 12).

As expected, these trials led to the conclusion that the drugs in question were not markedly less effective than the treatments with which they had been compared. This "non-inferiority" was enough for the regulatory authorities to grant marketing authorisation, and marketing authorisation was what mattered most to the companies concerned.

But studies of this type make a mockery of the concept of therapeutic advance. The investigators involved were fully aware that the outcome could only be this feeble, but were the thousands of patients who accepted to take a step into the unknown by taking these new drugs?

What patients and healthcare professionals need are substantial improvements in survival, quality of life, and safety. They are right to participate actively in sound clinical trials designed to demonstrate this type of therapeutic advance. In contrast, they would be well advised not to waste their time with "non-inferiority" trials that can only reinforce the status quo.

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