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## CORRESPONDENCE

### Commentaries on the article "Prospective, multicentric, comparative study between sleeve gastrectomy and Roux-en-Y gastric bypass, 277 patients, 3-years follow-up"



The study published by Catheline JM et al. [1] offers an excellent example of the difficulties of completing a randomized controlled trial in surgical practice according to the rules [2]. Initially designed as a randomized trial, given patients' refusal to be included after randomization in the bypass group, the study was transformed into a comparative prospective study. This led to imbalance between the two groups and an obvious lack of statistical power. Moreover, in 11 expert centers the study went on for fewer than 7 years. While one center included half of the patients (45%), the other 10 included an average of 15 patients, that is to say 2 patients a year. This observation could lead us to assume that the participating surgeons may have had a preference for sleeve gastrectomy. In addition, it would have been interesting to collect data over the 7 years on non-included patients. A useful alternative approach would have consisted in taking into account the patients refusing randomization, including them in a parallel group, and analyzing their results [3].

While from a methodological standpoint, the authors are to be commended for having reacted to the inclusion challenges and modified their method of analysis, the following two questions arise: (1) What new statistical method was set up when randomization gave way to observational study? (2) For what reason, when the study was initially designed, were the authors persuaded that in the event of non-inferiority, the results would favor sleeve gastrectomy?

The present study confirms the results of the most recent meta-analyses of randomized trials on the subject [4]. However, meta-analyses of randomized trials can be criticized for their low external validity (restrictive inclusion criteria in the trials under consideration in the meta-analysis), and observational trials can be criticized for their low internal validity (biases inherent to any retrospective study, or relevance of the well-known adage "garbage in garbage out"). Indeed, meta-analyses are hardly a panacea, and they do not constitute a definitive response to our questions [5]. It also matters to accept the fact that randomized trials have their

limits (feasibility, trial design duration, inclusion duration, inclusion criteria often too restrictive to allow for creation of a homogeneous group, costs, etc.) [6]. While it would be out of the question to put an end to randomized trials in surgical practice, it behooves us to have them conducted to the greatest possible extent under reasonable conditions.

That much said, a "Plan B" would most likely consist in the development of exhaustive prospective registries responding with an acceptable level of evidence to our day-to-day interrogations. Given that the SOFFCO-MM recently launched a large-scale registry, we may hope that a sizable number of bariatric surgeons will participate, and that the collected data will be reliable and interpretable.

#### Disclosure of interest

The author declares that he has no competing interest.

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K. Slim

*Digestive surgery unit, Clermont-Ferrand  
 University Hospital, CHU de Clermont-Ferrand, 1,  
 place Lucie-et-Raymond-Aubrac, 63003  
 Clermont-Ferrand, France*

*E-mail address: [kslim@chu-clermontferrand.fr](mailto:kslim@chu-clermontferrand.fr)  
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