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Medical journals and editorial quality control

We have read the article entitled *Sacubitril–valsartan in heart failure and multimorbidity patients* by Raquel Rodil *et al*.[1]

First, it drew our attention that table 1 reads that 13 individuals were dead at baseline out of 65 included patients. No drop outs were reported and results of all 65 patients were shown (table 2), which also challenges the veracity of data. There are many other methodology aspects to be pointed out like misreporting of side effects (not registered) or the fact that inclusion criteria mismatch the legal use of sacubitril–valsartan in Spain to name but a few. The authors begin the discussion section by saying that 'sacubitril-valsartan is a major breakthrough'. This statement cannot be derived from this uncontrolled, one arm biased study. If we believe the data authors report, all 65 patients were under treatment with sacubitril–valsartan at endpoint, which means they all tolerated valsartan. However, only 66% of them had 'pre-use' of ACE-i or ARBs, and we do not know how many patients were receiving these drugs at baseline. This means at least 34% patients had been poorly treated at baseline, and the improvement observed could be due to the addition of valsartan rather than to the combination sacubitril–valsartan.

The authors declared no conflicts of interest but all had received money from the manufacturer of sacubitril–valsartan during 2017 as the drug was actively being promoted.[2]

All this prompted us to contact the Research Ethics Committee. Last 3 September 2018, they confirmed this study was never submitted to the Committee. Neither was it registered in the database of the Department of Health of Navarre (Spain) nor in the database of the Spanish Medicines Agency, being both requirements also mandatory. On that day, we emailed the authors asking them to provide us with both the study protocol and data set. As of today, we have not received anything.

The ESC Heart Failure journal endorses the COPE Guidelines on good publication practice that read 'final protocol should form part of the research record' and also 'formal and documented ethical approval from an appropriately constituted research ethics committee is required for all studies'.[3] In this case, no legal nor ethical mandatory requirement was fulfilled, which justifies retraction of the article from the journal. We think this case should serve as an example of the necessity for medical journals to strengthen their proceedings to improve quality control of drafts submitted for publication.

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