



Dear Members,

IFSO would like to inform you about the official retraction of the article published in *Surgical Endoscopy* (Springer) titled: "**Long-term follow-up after sleeve gastrectomy versus Roux-en-Y gastric bypass versus one-anastomosis gastric bypass: a prospective randomized comparative study of weight loss and remission of comorbidities**" by Ruiz-Tovar J. et al.

This e-mail is intended to warn IFSO members not to quote this article in future publications, as this could reflect discredit on the entire bariatric community as RCTs are highly cited, and have to be included into systematic reviews, meta-analyses, bariatric guidelines, etc.

Attached to this e-mail you can find:

- \* [Letter to the editor about Ruiz-Tovar J. et al. publication](#)
- \* [Retracted paper of Ruiz-Tovar J. et al.](#)
- \* [Retraction note by Ruiz-Tovar J. et al.](#)
- \* [Ethic approval of Ruiz-Tovar J. et al.](#)
- \* [Ruiz-Tovar's RCTs published since 2017](#)
- \* [Clinical Trials Registrations of Ruiz-Tovar's RCTs](#)
- \* [CONSORT diagrams of Ruiz-Tovar's RCTs](#)

Ruiz-Tovar J. published a prospective randomized trial with 600 patients in *Surgical Endoscopy* (SE) in 2019

(Ruiz-Tovar J, Carbajo MA, Jimenez JM, Castro MJ, Gonzalez G, Ortiz-de-Solorzano J, Zubiaga L (2019) Long-term follow-up after sleeve gastrectomy versus Roux-en-Y gastric bypass versus one-anastomosis gastric bypass: a prospective randomized comparative study of weight loss and remission of comorbidities. (Surg Endosc 33:401–410.).

In March 2020, IFSO informed the Editors in Chief of Surgical Endoscopy (Prof. Mark Talamini and Prof. George Hanna) that we had severe concerns on the correctness of the data within this study. The group expressing the concerns wanted to publish a letter (see above) in SE, giving the authors a chance to reply and to have a scientific discussion.

The group signing this letter, amongst others, consists of the current IFSO President, IFSO President elect, five former IFSO Presidents, the current IFSO-EC President, IFSO-EC President elect, IFSO-EC past President, head IFSO-EC Scientific Committee, Member at Large IFSO-EC, and several other authorities in the bariatric field.

Unfortunately, SE did not publish that letter, but it eventually withdrew the publication by Ruiz-Tovar (see above retraction note) published on the 16th of January 2021).

Dr. Ruiz-Tovar claimed that they had identified errors in the transcription of data collected for the study to their database, which had made the results and conclusions unreliable.

On 2nd of December 2020, Dr. Ruiz-Tovar sent the Ethics committee „approval“ (see above). This was signed by the Dean of a Nursery School (no name written). This document was issued on 3rd of May 2010 from the University of Valladolid, and does not mention the word „randomized“. Attempts to contact the university were unsuccessful (because they must have the study protocol/calculations which are still missing until today).

**Up to date we have not received any study protocol, nor a power calculation, or any answer to our raised questions and concerns by Ruiz-Tovar J.**

The head of the hospital - Prof. Miguel Angel Carbajo - where the patients were operated, confirmed in a written statement that there was **no randomization at all** and that he did not confirm his co-authorship, as several of other co-authors.

***More details about the most important concerns in the mentioned publication:***

Ruiz-Tovar J. registered the study on [clinicaltrials.gov](https://clinicaltrials.gov) on 10th of March 2018

(<https://www.clinicaltrials.gov/ct2/show/NCT03467646?id=NCT03467646.&draw=2&rank=1>), (6 years after

recruiting the last patient, 18 days before submitting the paper to SE), claiming that he had forgotten to do so.

All RCTs, according to Good Clinical Practice (GCP) and CONSORT guidelines, MUST be registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) before recruiting the first patient.

The „Detailed Description“ on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) consists of 2 lines (!) – the same length as the „Brief Summary“. The same is true for all his „RCTs“.

Further, on [ClinicalTrials.gov](http://ClinicalTrials.gov) (and in the paper) the authors state that “patients were randomly assigned into 3 groups“ – a stratification (the only explanation for the equal sex distribution) is not mentioned (neither on [clinicaltrials.gov](http://clinicaltrials.gov) nor in the paper).

- CONSORT flowchart in the publication (falsely named „COHORT flowchart): **600 patients were assessed for eligibility** – and **all 600 patients were willing to get (and were) randomized**
- **All 600 patients underwent the planned operations.**

**No conversions, no change in operation** (e.g. due to adhesions).

- **All patients that were followed (91%) survived 5 years – not a single death. Probability:  $4.3 \times 10^{-14}$**
- The **internal hernia rate** without closing the defects in the **RYGB group was 2% after 5 years** (with a follow-up rate of 92%) in comparison to a 5.8-fold higher rate published in the literature.
- All 3 groups had the **same sex distribution without (mentioned) stratification – probability  $3.6 \times 10^{-141}$**
- And **several other concerns** mentioned in detail in the letter to the editor.

***Further investigations about previously published RCTs of Ruiz-Tovar J. offered us the following information:***

Ruiz-Tovar J. published 14 RCTs between 2017 to 2020 as a first author.

In all these studies, Ruiz-Tovar J. registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) **after** recruiting patients.

There is not any correct study protocol registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

These facts are a severe violation of good scientific practice, disables transparency and comprehensibility of the published articles.

The attached CONSORT diagrams of his RCTs further highlight that there **was not a single patient not willing to be randomized in these 14 RCTs.**

***To conclude:***

IFSO as the scientific society behind worldwide bariatric/metabolic surgery worked this case up in detail to further provide validity and integrity of science in the future.

IFSO informed the Spanish Society of Obesity Surgery (SECO) and the Spanish Association of Surgeons (AEC), which is investigating the case with lawyers.

In the meanwhile Dr. Ruiz Tovar withdrew his membership of SECO (Spanish Obesity Surgery Society) and is therefore no longer a member of IFSO.

Thank you for reading this long letter.

The IFSO Executive Board