Author’s response to reviews

**Title:** Laparoscopic Adjustable Banded Roux-en-Y gastric bypass as a primary procedure for the super-super-obese (Body Mass Index > 60kg/m2)

**Authors:**

Bruno Dillemans (bruno.dillemans@azbrugge.be)
Sanjay Agrawal (sanju_agrawal@hotmail.com)
Sebastiaan Van Cauwenberge (sebastiaan.vancauwenberge@azbrugge.be)
Els Van Dessel (els.vandessel@azbrugge.be)
Jan-Paul Mulier (jan.mulier@azbrugge.be)

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**Author’s response to reviews:** see over
Reviewer 1

I am interested in the details of your stapled laparoscopic gastric bypass technique. Specifically, what (if any) steps did you take to ensure that the band was not contaminated when the small bowel and gastric pouch were opened during the gastric bypass? In your conclusion, you state that “insertion of ABG is feasible and safe during a LRYGB at the primary operation with no immediate major complications.” I don’t think that a case series of 1 patient proves that this technique is generally safe or without major complications. It certainly seems feasible, but safe has yet to be determined.

For the details of our fully stapled laparoscopic gastric bypass technique we refer in the text to a previous published article by our group that extensively describes our technique. Concerning the placement of the gastric band during the same gastric bypass procedure we added the following text:

“Especially in the RYGB procedure, one may be concerned about possible band or port infection since, in contrast to the sleeve gastrectomy, both the gastric pouch and the small bowel are opened during the operation. Apart from the cefazoline given at induction, we did not take any special measures to avoid band contamination. One should of course try to limit excessive spillage of gastric or small bowel content during the operation by carefully opening the pouch or the bowel assisted by appropriate suction.”

In the initial article we indeed described only one case. Since we already performed six of those cases in total (as mentioned in the first cover letter), all without any complications, we decided to include all those patients in the article. So in the title of the article we deleted ‘first case’. From this point of view the article is not a case report anymore since we extended the series of included patients, giving the article more power regarding feasibility and safety. The total series of six patients is described by sex, mean age and mean BMI.
Reviewer 2

1. This manuscript describes a single case of bariatric surgery. According to the Journal's guidance "BMC Surgery does not consider case reports describing preventive or therapeutic interventions, as these generally require stronger evidence." Considering the present topic, the authors should probably collect information on some more RYGB-plus-AGB cases and then compare this group against patients, who have received RYGB or AGB alone.

In the initial article we indeed described only one case. Since we already performed six of those cases in total (as mentioned in the first cover letter), all without any complications, we decided to include all those patients in the article. So in the title of the article we deleted ‘first case’. From this point of view the article is not a case report anymore since we extended the series of included patients, giving the article more power regarding feasibility and safety. The total series of six patients is described by sex, mean age and mean BMI.

The main concept of the article is first of all the idea of placing a band during the RYGB procedure in super-super-obese patients to avoid a possible second procedure in this patient group since it has been proven that:
- RYGB is associated with a certain failure rate
- this failure rate seems to be higher in the super-super-obese patient group undergoing RYGB surgery
- adding an AGB on the failed RYGB achieves good results regarding further weight loss.

All those issues are addressed in the paper with the necessary references. Our principle idea is to add the AGB already during the first procedure in this particular patient subgroup. We agree that it is certainly interesting to compare this group to patients that received RYGB or AGB alone. It is indeed our purpose to analyze that concept in the future but of course more patients and a longer follow-up are required to do this. This is also stated in the conclusion of the article. On the other hand, lots of publications can be found that compare (non adjustable) banded-RYGB to non-banded-RYGB with better weight loss results in favor of the banded group. The only difference is that we use an adjustable band because we think that on the long-term there will be a better quality of life. This issue is now addressed in detail in the 'Discussion' section.

2. As the patient was followed up for only a few weeks after surgery, the authors’ conclusions are restricted to technical feasibility of the operation. Technical feasibility, however, cannot be considered as an argument on effectiveness. At least 1 but ideally 3 to 5 years of follow-up are required. It is important to note that the second part of the operation (AGB) will be "activated" by band inflation only 12 to 18 months after the initial surgery. It may well happen that major problems (such as slippage) will only be detectable after this period of time. This point is mentioned by the authors in discussion, but still it strongly weakens the value of the manuscript.

We completely agree with this important statement. However, the effectiveness already has been described by Gobble and by Bessler with follow-up periods of 13 months and up to 60 months respectively. Both authors use the band as a revisional procedure in patients that previously underwent RYGB surgery but that failed to achieve an acceptable excess weight loss. Long-term complications also seem to be very limited according to their series. We expect to see the same results when long-term follow-up is available regarding further weight loss and possible complications. Since it is generally stated that revisional
bariatric operations have a higher complication ratio (and what is also noted by Bessler in his series) we try to anticipate this problem by adding the band during the primary procedure. It is probably not warranted to place an AGB in all primary RYGB patients, so we limited ourselves to that group of patients in which the failure rate is expected to be the highest. From this point of view, our article is not that weak since we address two important issues:

− we want to omit a second operation (in probably still high-risk patients)
− we want to omit unnecessary complications associated with that second operation.

3. Even the very simple statement that the procedure was "safe" has no scientific basis. After just one case, it is still possible that the procedure produces major complications in half of the cases or even more.

We totally agree with this remark and this is also the reason why we extended our paper to our first six patients that already underwent this combined procedure. One has to take into account that all these patients (BMI > 60 kg/m²) are high-risk patients both surgery-related as well as anesthesia-related. But since indeed it is still difficult to draw a conclusion about the safety we use the statement ‘seems to be safe’.

4. The figures should be mentioned in the text. The legend to Figure 2 contains the word "sleeve gastrectomy", although the resection of the greater curvature is not mentioned as a step of the surgical procedure.

The figures are cited in the text and the legend is adjusted.

5. The surgical technique should be described in more detail:

As already mentioned above we use a full standardized surgical technique which we extensively described in an article that was published in ‘Obesity Surgery’. This article is cited in the text and the article is available via ‘Open Access’. Describing the whole technique again would take the attention away from the fact we add the band during the primary procedure. This is the reason why we in the ‘Surgical Technique’ section only focus on the key points of the addition of the band.

- How long were the limbs of the Roux-en-Y gastric bypass. The simple statement of a "long limb" is too vague.

This issue is addressed using the following sentence:

‘Since all patients had a BMI > 50kg/m², the length of the alimentary limb was measured at 200 cm.’

- Was the stomach divided in exactly the same way as in a "normal" RYGB case? How large was the gastric pouch? Was the size calibrated in any way?

Since the creation of the gastric pouch is not different than that of a normal non-banded RYGB we mention the following sentence:

‘Since we perform a standardized fully stapled laparoscopic RYGB procedure, the procedure started with the creation of the gastric pouch following the same principles as previously published by our group.’
Was the fixation of the band done in any other way as in a "normal" AGB operation? One could assume that the diameter of the gastric remnant after RYGB is smaller than in a "normal" AGB case.

'To prevent slippage, the band was then fixed by suturing the gastric remnant to the gastric pouch both above and below the band with nonabsorbable sutures (2/0 Ethibond, Ethicon).

This sentence describes very well the fixation technique since there is, to our knowledge, no 'gastric remnant' in a 'normal' AGB case.

6. It would be interesting to know why this very special case was selected for the RYGB-plus-AGB procedure. The authors only mention a multidisciplinary discussion regarding the choice of the operation. If there were any predictors of RYGB failure (e.g. super-obesity, eating habits, etc.) in the literature, these criteria should be described.

We initially described our very first case that we performed. Regarding the debate on 'case report', as discussed above, we included the other patients that we operated on for the same procedure until March 2010.

Since almost no literature data is available regarding criteria that would predict RYGB-failure, we cannot describe those criteria. However what has been published in literature is the fact that super-super-obese patients have a less optimal result regarding excess weight loss and we mention and refer that in the article as such:

'Also, percent EWL is significantly less after 1-year in the super-super-obese group as compared with the less obese group and many patients are still technically considered to be obese (lowest post-surgical BMI > 35) following RYGB surgery in the super-super obese group.'


7. The pros and cons of early versus delayed filling of the band should be discussed. Is earlier band filling an option, since the procedure "combines the potential benefits of RYGBP and AGB"?

The first action mechanism for weight loss will be the RYGB (first 12-18 months as has been shown in literature). Then, when weight stabilizes, additional restriction can be achieved by inflation of the band, causing further weight loss.

One of the most important reasons of failure after RYGB is the fact that patients loose restriction over time due to pouch dilatation or due to dilatation of the gastro-jejunal anastomosis. The band can counteract this.

'With the combined procedure, a sequential action mechanism for weight loss is to be expected. The restrictive, malabsorptive and hormonal working mechanism of the RYGB will induce weight loss from the start reaching a stabilised plateau of weight after 12 – 18 months. At that time, filling of the band can be started resulting in further gastric pouch
restriction and increased weight loss. Moreover, besides improving the results of total weight loss, a gradual filling of the band can as well prevent the RYGB patient from weight regain if restriction would fade away with time.'

Although early band filling could be an option, we plan to evaluate and to measure the potential additional benefit of the band on the weight loss. From this point of view we opt to start filling the band after weight loss has reached a plateau.