UNIVERSITÀ DEGLI STUDI DI NAPOLI "FEDERICO II" – SCUOLA DI MEDICINA E CHIRURGIA

Dipartimento Universitario di Medicina Clinica e Chirurgia

Dipartimento ad Attività Integrata di Endocrinologia, Gastroenterologia e Chirurgia
U. O. C. Centralizzata di Endoscopia Digestiva Operatoria

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Title STAPLE-LINE LEAK AFTER SLEVE GASTRECTOMY IN OBESE PATIENTS: A HOT TOPIC IN BARIATRIC SURGERY. ARE NEW STENTS TURNING ENDOSCOPIST INTO SURGEON'S NUMBER ONE ALLY?

Authors Giuseppe Galloro, Simona Ruggiero, Teresa Russo, Alessandro Telesca, Mario Musella, Marco Milone, Raffaele Manta

Name of Journal: *World Journal of Gastrointestinal Endoscopy*

Dear Editors,

Thank you for your e-mail of November 30, 2006.
We have read with interest the comments of the Reviewers and of the Editorial Board.
We are very pleased to resubmit a revised version of our manuscript. In this new version we did our best to accomplish the Reviewers' suggestions. All the points raised were addressed either in the point-by-point reply to the Reviewers and the Editorial Board's comments and/or in the revised version.
All the added paragraphs are typed in red-underlined characters.
References and typesetting were corrected

Here are our responses to each of the Reviewer's comments listed.

Reviewer 1
We are very glad about the Reviewer opinion and we thank Her/Him.

Reviewer 2
1) We thank the Reviewer for Her/His remark. Actually the placement of stents is still not widely performed. For this reason we add at pg 4 – line 18: even if this is not a widely accepted treatment. The mehods to select the patients for the placement of covered stents are listed at pg 10 – lines 25-32.

2) The Reviewer says *"… Author should introduce different methods for prevention of staple-line leak, then compare them".* Really, in order to reduce the rate of staple-line leak, the use of several and different buttress material associated with the stapler has been advised. Nevertheless the results are very disappointing and low, and there are no statistical evidences to support this kind of solution. In confirmation of this, a big number of papers and statements are published pointing in this direction, even if we have cited just the reference n° 29 for matter of space.

3) The Reviewer says *"…The section of paper should be more accurate, and author could make a meta analysis if possible compare them".*
We thank the Reviewer for Her/His suggestion but I would respectfully remember that this paper is an invited editorial. This kind of article is submitted by editorial board members whose are invited to make

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comments on an important topic in their field, regarding current research status and future directions that will promote development of this discipline.

On the other hand, a meta-analysis is a kind of article comprising statistical methods for contrasting and combining results from different studies in the hope of identifying patterns among study results, sources of disagreement among those results, or other interesting relationships that may come to light in the context of multiple studies.
The target and motivation of a meta analysis are basically different from those of an editorial and I think that the insertion of metanalytic data could distort the sense of an editorial.
However we thank the Reviewer for Her/His suggestion and we will evaluate the opportunity to prepare a meta analysis about this matter in the near future.

Reviewer 3

The Reviewer says *"… whether the stent could be removed and whether intra-membrane stent could be applied should be further mentioned. If one has to wear the stent for a lifetime just to treat anastomotic leakage, then the loss outweighs the gain".*
We thank the Reviewer for Her/His remark. The treatment by Megastent goes on for a period of 7-9 weeks and do not is a lifetime therapy, obviously. Anyway this data laks in our paper and, in the revised release, we add at pg 6 – line 4 In our patients one week after the stent placement a liquid high protein diet was started, followed by a soft diet and discharge 3 days later. The stent was removed after 8 or 9 weeks and an upper endoscopy documented complete healing of the leak.

Reviewer 4

1) The Reviewer says *"…Please change the manuscript into "the journal style".*
We thank the Reviewer for Her/His suggestion but I would respectfully remember that this paper is an invited editorial and has been written following the instruction for the editorials of WJGE.

2) The Reviewer asks *"…What is the gold standard treatment of staple-line leak after sleeve gastrectomy"?*
Nowadays there is not a treatment that we can universally consider the gold standard for staple-line leak after sleeve gastrectomy. A proper treatment of leaks after 12 weeks from the operation should be a fistula-jejunostomy (open or laparoscopic depending on the surgical skills). On the other hand, according to best practice guidelines from the International Sleve Gastrectomy Expert Panel Consensus (R. J. Rosenthal and International Sleeve Gastrectomy Expert Panel: International Sleeve Gastrectomy Expert Panel Consensus Statement: best practice guidelines based on experience of > 12,000 cases. Surgery for Obesity and Related Diseases 2012; 8: 8–19) stents were an appropriate treatment for leaks within 12 weeks from the operation. Unfortunately in this case the migration of esophageal stent reach up to 50%. For these reasons the results from Megastents, even if limited in numebers, are very interesting and as Gagner says: … . If Megastent will solve the migration problem seen in earlier series, as well as take care of the mid-body stricture often associated, then we might see less fistula-jejunostomies in the near future …".

3) The Reviewer says *"…This procedure needed the experienced surgeon. It could not apply this in the other hospitals".*
We agree with the Reviewer. The bariatric surgery is a particular field of surgery that needs a specific and super-specialized team: surgeons, nutritionists, endoscopists etc. This is true more and more in case of post-operative complications as staple-line leak after sleve gastrectomy. For these reasons we recommend that the complicated multi-disciplinary management of obese patients with gastric leakage treated by stent graft should be confined to specialized centers (pg 6 – line 14).

4) The Reviewer asks to discuss the issue *"The use of esophageal stent for prevention of staple-line leak after sleeve gastrectomy in high-risk patients".*

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To our knowledge, and after to ask in PubMed and Scopus, there is no defined role for the esophageal stent in prevention of staple-line leak after sleeve gastrectomy in high-risk patients.

5) The Reviewer says *"Unfortunately, the authors did not show the cost-effectiveness of the study".*
We thank the Reviewer for Her/His remark. Unfortunately nowadays there are not studies comparing costs of operative repair versus stent repair of staple-line leak after sleve gastrectomy. Our series is too small (8 patients have completed the treatment and other 3 are still in coming) to extrapolate pharmaco-economic data. For sure we can say that in our patients Megastent placement seems to be as effective as surgical repair. Moreover, stent placement resuls in a shorter length of stay, lower rates of morbidity, and lower costs when compared with traditional surgical repair.
Anyway, there is an interesting paper (R K. Freeman, A. Herrera, A. J. Ascioti, M. Dake, R. S. Mahidhara: *A propensity-matched comparison of cost and outcomes after esophageal stent placement or primary surgical repair for iatrogenic esophageal perforation.* J Thorac Cardiovasc Surg 2015 Feb 11. pii: S0022-5223(15)00129-4. doi: 10.1016/j.jtcvs.2015.01.066. [Epub ahead of print]) in wich the Authors compare cost and outcomes of esophageal stent placement versus primary surgical repair for iatrogenic esophageal perforation. The results are completely favourable to the stent therapy, about outcomes and cost too.
We agree with the Reviewer about the opportunity of a cost-effectiveness study and it will be an interesting issue for a new paper with a bigger series.

6) The Reviewer suggests *"Authors should to recommend the readers to apply this knowledge into routine clinical practice".*
We are very glad and proud about the Reviewer's suggestion an we will do this as soon as we will have wider data supporting our conclusion.

We look forward to hearing from you.
I send my best regards.

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