Author's response to reviews

Title: The laparoscopic hiatoplasty with antireflux surgery is a safe and effective procedure to repair giant hiatal hernia

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Author's response to reviews: see over
Rebuttal letter

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MS TITLE: The laparoscopic hiatoplasty with antireflux surgery is a safe and effective procedure to repair giant hiatal hernia

We are really grateful to Reviewers for their suggestions extremely helpful in the efforts to revise and improve our manuscript.

Referee 1

Comment 1:

Abstract/Conclusion: The lack of a control group does not allow any comment on the reduction of hernia recurrence by the technique described.

Response:

We re-elaborated the abstract conclusion, stating that all patients were satisfied of procedure and no hernia recurrence was recorded in the study group, treated respecting several crucial surgical principles, e.g., complete sac excision, appropriate crural closure, also with direct hiatal defect where possible, and routine use of antireflux procedure.
Comment 2:

Patients and methods: Three patients were excluded due to “absolute contraindications to laparoscopic approach”. Please detail these contraindications.

Response:

Two patients were not able to tolerate general anesthesia and an open approach with combined spinal-segmental thoracic epidural anaesthesia alone was indispensable; on the other hand the third patient was affected by chronic liver disease with refractory coagulopathy.

Such detailed description has been added in the revised manuscript (see patients and methods section, page 4)

Comment 3:

Methods/Results: The use of PPI pre- and postoperatively should be added

Response:

Sixteen patients with giant hiatal hernia were treated at the 8th General and Gastrointestinal Surgery Centre after treatment, for at least 3 months, with omeprazole at 80 mg daily. All patients were treated postoperatively with preventive omeprazole 40 mg daily therapy per os for one month.

Such detailed description has been added in the revised manuscript (see patients and methods section, page 4 and page 11)
Comment 4:

Methods: Description of oesophageal manometry and 24h pH impedance measurement should be shortened

Response:

We re-elaborated the methods section.

Comment 5:

Were all patients available for the different tests up to 12 months postoperatively?

Response:

All patients completed the follow up assessment 12 months postoperatively. Such detailed description has been added in the revised manuscript (see follow up assessment section, pages 13, 14)

Comment 6:

In the preoperative workup of giant hiatal hernias, manometry and pH metry are often not reasonable to perform due to the difficulty in localizing the gastroesophageal junction. Obviously, you did not have any corresponding problems in your series. Please comment.

Response:

Manometry, pH metry and bilimetry are not always technically possible in giant hiatal hernia, especially in giant hernias with rotation. In our study group we performed correctly these
tests in all cases. Functional oesophageal tests was conducted by very expert operator after radiologic and endoscopic examination; therefore anatomic and morphological informations given by these tests facilitated enormously the functional gastro-esophageal junction localization. However, as a consequence of the technical difficulty, we have to highlight that the duration of functional tests was significantly higher than in patients without giant hiatal hernia.

Comment 7:

Surgical procedure: the mesh type used should be detailed. Meanwhile it is well known, that the use of ProTack at the hiatus is hazardous. Why did you use these tackes? Please comment.

Response:

We added the used mesh type detail: Intramesh®T1 (Cousin Biotech, Wervicq-Sud, France). Such description has been added in the revised manuscript (see surgical procedure section, page 10).

As regard the use of the ProTack at the hiatus, we well know that the actual firing of the ProTack can be a tricky maneuver because accidental stapler deployment can injure the heart, which can result in a fatal outcome. The precise technical details of stapling the mesh to the diaphragm with proximity of the heart are difficult to illustrate in written form. The surgeon must use enough pressure on the stapler to ensure that the ProTack penetrates the prosthesis and secures an adequate tissue bite but not so much pressure that the ProTack penetrates the diaphragm and breaches the pericardium. The attainment of this skill is facilitated with training, anatomic knowledge, and experience. Therefore, also encouraged by
the results of Champion JK\textsuperscript{1}, Keidar A\textsuperscript{2}, Frantzides CT and Carlson MA\textsuperscript{3} we decided to use these tacks.

Comment 8:

Figure 5 and Figure 6 does not provide additional information and should be omitted.

Response:

We removed figure 5 and figure 6.

Comment 9:

Postoperative LOS pressure is mentioned to be significantly lower than preoperative. Do you mean higher?

Response:

Yes, I do. We performed the correction.

Such detailed description has been added in the revised manuscript (see follow up assessment section, page 13)

Comment 10:

Detailed information with focus in pre- and postoperative impedance data (gas reflux, liquid reflux, symptom index) would significantly add to the study and enable characterization of pre- and postoperative reflux in patients with hiatal hernias.

Response:

We integrated our study with the requested informations.

- “The Symptom Index, defined as the percentage of symptoms associated with preceding reflux episodes occurring within 5 minutes time window obtained by dividing the total number of symptoms, was considered positive when ≥50%. The number of liquid and gas reflux episodes were also evaluated”

Such detailed description has been added in the revised manuscript (see Combined pH and impedance data analysis section, page 7)

- “moreover the Symptom Index was positive in 11 patients (84.6%). Concerning the refluxate characteristics, the mean of liquid reflux episodes was 28.5±8.1 and the mean of gas reflux episodes was 14.7±5.”

Such detailed description has been added in the revised manuscript (see Preoperative findings section, page 12)

- “Interestingly, the postoperative percentage of Symptom Index was significantly lower than preoperative value (7.7% versus 84.6% respectively, p<0.05). Furthermore, as concern the refluxate characteristics, the postoperative liquid reflux episodes mean of 21±7.4 was significantly less frequent compared to 28.5±8.1 of preoperative analysis, p<0.0001, as well as the postoperative mean of gas reflux episodes (postoperative mean of 10.5±5.1 versus preoperative mean of 14.7±5, p<0.05).”

Such detailed description has been added in the revised manuscript (see Follow-up assessment section, page 13)

- “Furthermore we documented a reduction of liquid and gas reflux episodes after surgery, as a probable consequence of total fundoplication hindrance on the transient lower
oesophageal sphincter relaxations due to the compression on the lower oesophageal sphincter segment, complying the observations of Linke GR et al [67].”


Comment 11:

Discussion: Potential mesh related complications are mentioned. However, mesh related complications were mostly observed using PTFE-meshes. Complications with polypropylene have only been reported, to my knowledge, in four cases so far. However, the true rate of mesh-related complications is unknown. This aspect should me mentioned.

Response:

We integrated the mesh related complications aspect, with the addition of 2 new references:

“*We believe that it is possible to get satisfactory results even without using these devices, with the possibility of efficacy lost over long time, avoiding serious complications predicted by some authors in relation to the different type of meshes [58-62]: erosion or migration of the mesh into the esophagus or stomach, as well as complications due to severe mesh adhesions, infection, or the development of fibrotic strictures in the hiatal region. Although different series report complication rates from 1.3% [62] to 20% [58,63], the true rate of mesh-related complications is currently unknown [64], probably due to the lack of long-term follow-up studies.*”

Referee 2

Comment 1:

In "Patients and Methods" the authors dwell too much on the description of well-standardize procedures. So, I'd shorten the description of oesophageal manometry, esophageal impedance/pH monitoring, multichannel impedance data analysis, bilirubin monitoring and bilirubin data analysis.

Response:

We re-elaborated the methods section.

Comment 2:

In "follow-up assessment" section the authors conclude that 12 months after surgery neo-high pressure zone has a mean-value of 21.2 mmHg, significantly lower than preoperative value. But the preoperative value is 9.3 mmHg so I guess the authors mean neo-high pressure zone has a mean-value of 21.2 mmHg, significantly higher than preoperative value.

Response:

We performed the correction.

Such detailed description has been added in the revised manuscript (see follow up assessment section, page 13)