Author's response to reviews

Title: The Sigma-trial protocol: A prospective double-blind multi-centre comparison of laparoscopic versus open elective sigmoid resection in patients with symptomatic diverticulitis

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Version: 3 Date: 15 June 2007

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15-06-2007

Dear Sir / Madam,

Thank you very much for the positive peer review of our manuscript. The reviewer, dr. M.K. Diener, had suggestions on eight issues. All of these issues have been revised, according to suggestions made.

1. Abstract: The aim / goal of the trial is not precisely formulated in the abstract. It would be useful to include one sentence at the end of the background section like "The sigma trial is designed to evaluate the effectiveness of lap. versus conv..."

Revision: The Sigma-trial is designed to evaluate the presumed advantages of laparoscopic over open sigmoid resections in patients with symptomatic diverticulitis.

2. Abstract: How is postoperative morbidity defined? When is it measured?

Revision: We divided morbidity in minor (e.g. wound infection), major (e.g. anastomotic leakage) and late (e.g. incisional hernias) complications, data will be collected during hospital stay and after six weeks and six months postoperative.
3. Abstract /Discussion: 2nd line "to define the role of laparoscopic treatment" - "to define the role of lap sigmoid resection" would be more straightforward.

Revision: The Sigma-trial is a prospective, multi-center, double-blind, randomized study to define the role of laparoscopic sigmoid resection in patients with symptomatic diverticulitis.

4. Methods & Design / Endpoints: Again, how is the primary endpoint defined in detail and when is it measured? The second sentence of this paragraph is confusing, something missing? Please keep in mind that the primary endpoint is the very basic and essential item of the trial. So it cannot be specified and defined enough (e.g. definitions of clinical outcome parameter such as anastomotic leakage, abscess, wound infection etc. should be defined).

Revision: Primary endpoints of the study are postoperative morbidity and mortality. Minor complications are defined as wound infections, urine tract infections pneumonia, venous thrombosis or other. Major complications consist of anastomotic leakages, postoperative haemorrhage, intra-abdominal abscesses, re-operations and other within the first four postoperative weeks. Data concerning late complications after four weeks are collected at the outpatient clinic six months postoperative (i.e. incisional hernia, ileus or other).

When the endpoints are measured is described in 'Data collection and statistics'.

5. Methods & Design /Participating surgeons and clinics: could you give a reference for the statement regarding the learning curve effect?

Revision: Reference 22 shows that approximately 11 to 15 completed laparoscopic colectomies are needed to comfortably learn this procedure, using total operative time as an indication of learning.


6. Methods & Design /Randomization: Postoperative dressing refers to blinding not to randomization (might be confusing in this paragraph). Moreover, how long will the opaque dressing be maintained? How will it be changed? Please specify, if possible.

Revision: The paragraph is now called 'Randomization and blinding', the duration is five days. Further details on the blinding method are described in the paragraph 'Postoperative management'.

7. Methods & Design: The Protocol publication would potentially benefit from
specification of the study hypothesis (H0 / H1 hypothesis). Also, statistical methods of analysis should be defined such as per-protocol versus ITT Analysis, planned interims analysis etc.

Revision: Our hypothesis is that patients undergoing laparoscopic sigmoid resection have fewer complications, less pain and earlier discharge from the hospital.

We added a paragraph called 'Data collection and statistics', which covers the statistical methods: An SPSS-database will be created with all required parameters. Data analysis will be performed in accordance with the intention to treat principle. Groups will be compared using an Independent Samples T-test where appropriate, otherwise a Wilcoxon or Chi-square tests. Painscores will be analysed using repeated measures analysis.

8. Specification of surgical technique: how will the anastomosis in the open group be performed? However, the manual for the surgical technique is very well done.

Revision: It is not always necessary to mobilize the splenic flexure in order to create a tension free anastomosis. The distal margin is made to the anatomic rectum, which can be identified by the loss of the taeniae coli. No diverticulae should be placed in the anastomosis. Usually a double-stapled anastomosis is created.

I hope these revisions are in accordance with the suggestions made. I will upload the revised version immediately, and I hope you will consider publication of the manuscript.

Kind regards,

Bastiaan Klarenbeek