Author's response to reviews

Title: Perioperative management in distal pancreatectomy: Results of a survey in 23 European participating centres of the DISPACT trial (ISRCTN 18452029) and a review of literature

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Author's response to reviews: see over
Dear Editors:

Thank you very much for the reconsideration of our revised manuscript “Perioperative management in distal pancreatectomy: Results of a survey in 23 European centres and a review of literature”, Ms: 8407816823598167 for publication in Trials. Please find below a point by point response to the reviewers critique as suggested. The manuscript has been revised accordingly and changes are highlighted in a comparison copy provided for your convenience.

Moreover, the manuscript has been carefully edited by a second native speaker.

Editor remarks:

The Editor and reviewer 2 wanted to know whether ethical approval was required for the study. While no ethical approval was necessary for the survey according to the institutional guidelines and applicable laws, ethical approval was required for the DISPACT-trial. The study has been approved by the ethics committee and has been registered (ISRCTN 18452029). The authors agree that this is vital information for our manuscript and have added this information to both abstract and introduction.

The editorial board and reviewer 2 also suggested further language editing of our manuscript. The manuscript has carefully been edited by two native speakers (D.P.R. and H.K.).

Reviewer remarks:

Reviewer: Stefan Sauerland

1. Although the authors mention the association between caseload and outcome in the introduction, they fail to characterize their 23 centres. Were all these centres university hospitals operating on large number of patients per year?

   We have characterized the 23 participating centers and added a new table 1 to the manuscript. It lists the centre, number of pancreatic resections, distal pancreatectomies and randomized patients for the DISPACT-trial within the year 2008.

2. Are there any explanatory variables which are responsible for the differences in perioperative care? For example, was the use of octreotide or bowel preparation dependent on the caseload or the geographic localization of a centre?
This is an interesting hypothesis we have not investigated in our survey. Almost all centres are University hospitals and have a broad experience in pancreatic surgery. It was not our aim to explore further why there are differences. The aim was to demonstrate the current practice and we currently think about how we can design a study to investigate why there are these differences. Therefore we will contact the reviewer in the near future for his advice on this topic.

3. As this article describes the method of a consensus-assisted study protocol development, it would be fair to cite the German pioneer in this field: Lorenz W, Weitzerl F, Sitter H: Consensus-assisted development of a study protocol on sepsis: an important difference from previous randomised trials. Theor Surg 1994; 9: 63-67.

This reference was indeed missing and we have added it.

4. On pages 9 and 13, the word "aneurysm" should be spelled with "Y".

We have corrected the misspelling.

Reviewer: Fiona Simpson

1. Methods section, first word: Please amend the word survey (bolded) to read ‘Survey of current practice’ in your manuscript. This should also be changed in the results section, first word of the manuscript.

The word survey has been amended to ‘Survey of current practice’, in the method and result section of the manuscript.

2. Was ethics approval required to conduct this study? Please address this in your manuscript.

This study was a survey about current practice and not about individual patient data. Therefore no ethical consent and approval was required for this study according to local and international guidelines and laws. The DISPACT-trial has been approved by all local ethics committees of the participating hospitals. We have mentioned this in our manuscript.

3. Please provide a section in the methods of your manuscript describing the standardized questionnaire. This includes addressing who developed the survey, whether pilot testing was undertaken, who administered the survey, what mode
was used to administer the survey, which profession/s were surveyed in each of the 23 institutions, the number of people surveyed in each of the 23 institutions and how was the survey returned.

A new paragraph has been added to the methods part giving the details as requested.

4. Please include a copy of the survey instrument in the appendix of the manuscript.

A copy of the survey instrument has been added to the manuscript as Appendix 1.

5. In your manuscript please provide more of a description of the DISPACT trial, including basic demographic details of the 23 centres taking part in the (DISPACT) trial. For example are the facilities adult or pediatric, what is the size of each of the facilities, is the trial focusing on ward or intensive care recruitment. Is there a trial registry number for the DISPACT trial – if so please provide it in the manuscript. If there is a trial protocol paper already published please reference it so readers can read more about the trial if desired.

We have characterized the participating centres and added a new table 1 giving details about the institutions. Also more details about the ongoing trial have been added in the introduction part of the manuscript. A reference about the website (http://www.dispact.de/) has been added and the published study protocol is now mentioned (Diener et al., Clin Trials. 2008;5(5):534-45.). The trial registration number has been added.

6. Methods section, second paragraph: Please amend the word literature (bolded) to read ‘Literature search of best practice’ in your manuscript. This should also be changed in the results section of your manuscript.

The word literature has been amended to ‘Literature search of best practice’ in the methods and results sections of the manuscript.

7. The literature search was performed independently by three authors. Please describe in your manuscript who manually cross-searched additional publications and screened titles/abstracts/full text articles.

The additional literature research was performed by N.N.R., T.L. and H.B. and supervised by C.M.S. This information has been added to the methods part.
8. In your manuscript, please provide the terms used to filter the search for study design (and add to table as per point 2 in discretionary revisions). We have added the terms used to filter the search for study design and added this data to table 2, which now displays the full search algorithms.

9. In your manuscript, please describe whether you limited your search by language, what your search dates were, and whether you searched any other electronic databases other than Medline.

   No other literature databases than medline were searched and subsequent analysis of the identified literature was performed. All published articles were evaluated.

10. Please remove the second and third sentences in the survey section. I think these are relevant to the literature search section.

   The first paragraph of the results part of the manuscript was rewritten.

11. Please change the word antibiosis to antibiotics in all instances throughout the manuscript.

   The word antibiosis has been changed to antibiotics throughout the manuscript.

12. Literature search section: Throughout your manuscript, please put the reference numbers immediately after referring to the authors or studies. For example, in the ‘literature search bowel preparation paragraph’: please provide the references of the two meta-analysis directly after reference to them so the reader does not have to look through the seven references listed at the end of the first sentence to work out which two are relevant.

   The citation style was changed as requested throughout the manuscript.

13. Literature search section, bowel preparation: In your manuscript, please support your statement that the two meta-analyses found beneficial effects of no bowel preparation by explicitly providing the p-values of each outcome from each individual meta-analysis. Additionally, for the two of six RCTs included in one of the meta-analyses please specify which meta-analysis you are referring to, and
provide the effect sizes and p-values of each individual RCT so the reader can read the individual supportive RCTs if desired.

P-values for the two meta-analysis that did not find beneficial effects of bowel preparation were added. These p-values and p-values and effect-sizes for two of six RCTs have been added to the manuscript text and the corresponding table, respectively.

14. Literature search section, feeding regimens: Please describe in the manuscript what you mean by ‘early’ and ‘late’ postoperative return to oral diet.

A definition of early and late postoperative return to oral diet is given in the discussion part. Early is day one and two after a procedure and late is after three days after surgery.

Discretionary Revisions:

1. Please spell out in full ‘ICU’ and ‘IMC’ acronyms in the method section before shortening them throughout the manuscript.

   ‘ICU’ and ‘IMC’ acronyms have been spelled out before first appearance in the manuscript text.

2. Please consider putting the Medline search terms in a separate table and removing them from the body of the text.

   A table with medline search terms has been added to the text (Table 2). Search terms have been removed from the body of the text.

We hope that the revised manuscript is now suitable for publication in Trials.

Sincerely,

Christoph M. Seiler, MD, MSc                Helge Bruns, MD
Consultant Surgeon