Author's response to reviews

Title: The effect of changing the sequence of cuff inflation and device fixation with the LMA-Supreme(R) on device position, ventilatory complications, and airway morbidity: a clinical and fibrescopic study

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Author's response to reviews:

Dear Ms. Costoy,

We have read the detailed comments of the reviewers and would like to thank them for the care with which they read our manuscript and made their recommendations.

We have incorporated most of these comments and remarks into the revised version of our manuscript. Whenever this was not the case we have described in detail our reasons for not doing so.

We have expanded the abstract to include more information as requested - we had misread the instructions and were under the impression that the abstract should not be longer than 150 words.

We have added the requested information regarding the ethics committee and the public registry to the Patients and Methods section,

“This prospective, randomised study was approved by our institutional clinical study review board (Ethikkommission der Universitätsmedizin Göttingen) and registered in a publicly available registry under the number DRKS00003174.”

We have also added the Authors' Contributions, Competing Interests and Acknowledgement sections.

The references are formatted according to the BMC guidelines.

Two reviewers rightly criticised the sentence "There has been some speculation about whether ...." (Introduction, para 2, line 1), although it accurately describes how the study came about. The idea arose in the course of a conversation with Dr. Archie Brain, the "father" of the LMA, at a speakers' dinner after an LMA symposium. There was no previous work on which this was based; it was pure
speculation.

We have changed the sentence now to read

"Based on theoretical considerations, we hypothesised that the sequence of inflating the cuff and fastening the tube might influence both the seating of the cuff as well as the factors causing airway morbidity". We hope that this might be acceptable.

In the following we describe in detail how we dealt with each comment.

Reviewer 1 (Dawn Dillman)

1. Why was 60 cmH2O chosen as cuff inflation pressure?

We do not consistently use this pressure in our clinical practice, but we wanted to have consistency in the participants.

We have now described our reasons in the discussion

"The employed cuff inflation pressure that was at the upper limit of the manufacturer's recommendation could have contributed to the observed high incidence of postoperative airway morbidity in the control group. In clinical practice we use a cuff pressure that is just sufficient to give a tidal volume of 6 ml kg body weight-1 without air leak. But since this inter-individually differing pressure would have been a confounding factor we decided to use one standard pressure for all patients. We normally use this pressure for studies12, since it is the one most likely to allow sufficient ventilation in the greatest number of patients, but which is still within the limits set by the manufacturer.." (Discussion, 2nd to last paragraph)

2. Long ago it was common practice to use a local anaesthetic gel for lubricating supraglottic devices (and tracheal tubes), but as the many disadvantages of this became evident we switched to the water-based, non-LA-containing lubricant that is used for endoscopes and TEE probes (Endosgel®). This information has been added to the methods section.

"... one investigator (IB) inserted the lubricated (Endosgel®, Farco-Pharma, Cologne, Germany) LMA-Supreme® device ...".

3. Yes, we did forget to mention when the LMA was removed from the patient (also commented on by Reviewer 3). This has been added to the methods section.

"We removed the LMA when the patient was breathing spontaneously and muscle tone had returned to the jaw."

Reviewer 2 (Konrad Schwarzkopf)

"Minor essential revisions"

1. The reviewer requests that the relevance of the complications described in the cited literature be explained in the introduction.

We have decided not to comply with this request for the following reasons:
The introduction is not intended to be a review of the various models of supraglottic devices and the incidence of the various types of complications associated with their use. We cited the studies describing the various problems that still occur simply as justification of the present study with its attempt to reduce the incidence and severity of certain particular problems.

It should be obvious to the reader that some problems will have a greater impact on the use of the device (e.g. impossible to ventilate) than others (sore throat), but we have expanded the sentence listing the complications and now indicate their severity:

"These complications range from serious, e.g. the inability to adequately ventilate the patient's lungs, potentially serious, as an insufficient separation of the gastrointestinal and respiratory tracts to minor complaints such as postoperative dysphagia, hoarseness and sore throat." (Introduction, para 1)

However, it is our opinion that describing in any detail which complication occurred with which frequency in which published study would unnecessarily increase the length of the introduction. Whenever relevant to the results of the present study this information has been included in the discussion.

2. We did neglect to state clearly what the respirator settings were during surgery.

This information has been added to the methods section:

"For surgery the respirator was in pressure-control mode with the following settings: PEEP 5 cmH2O, Pmax sufficient to give a tidal volume of at least 6 ml.kg body weight-1 and a respiratory rate adjusted to keep end-tidal CO2 between 4.8 and 5.6 kPa."

"Major revision compulsory"
#1, sentence 1: "The authors should mention that the results of this study are limited to the use of this special LMA used in the described way."

Whereas this caveat should always be clear for any clinical study, we have added this to the last paragraph of the discussion in which we describe the limitations of the study.

"The results of the present study apply to the LMA-Supreme® inserted as recommended by the manufacturer and blocked to a cuff pressure of 60 cmH2O."

#1, sentence 2 and #2: "They should mention that in daily practice often other techniques for positioning are used" and "... describing other established techniques for insertion and fixation of laryngeal masks in general to demonstrate that in reality a lot of the first recommendations regarding the introduction of these masks are outperformed [...] today. So should the authors mention that in some departments LMA are used without any fixation at all".

Although it may well be as the reviewer claims, that other methods of insertion and fixation or no fixation at all are practiced in some institutions, we are not aware of this. Our department was one of the first in Germany to use the LMA in
close collaboration with Dr. Archie Brain, the developer of the original LMA, and some of the manufacturers' instructions for various devices are based on the results of our own studies. We have always taught and used the methods for insertion, testing and fixation given in the manufacturers' instructions leaflet, and we have no personal experience of aberrant methods of using the devices. It would therefore be hearsay for us to mention these methods in any detail - hardly the stuff of a scientific publication.

We have added the following sentence

"Any other method of inserting, affixing or otherwise using the device might, of course, affect the results in an unpredictable manner" to the discussion.

#3 Successful ventilation is the number one criterion for using an LMA and that is why we placed the greatest emphasis on it. A second important criterion is the separation of the gastrointestinal and respiratory tracts, which is the other point made in this study (position of the device tip in the upper oesophagus sphincter.)

We have stressed this point in the discussion.

Reviewer 3 (Pavel Michalek)
"Minor essential revisions"

Abstract: We have expanded the abstract as mentioned above. In this, the conclusions now state that no difference was observed in sealing pressures or insertion success rates. We do not believe that the patients in the study group were less "prone" to ventilation difficulties caused by glottic narrowing (which would imply some innate predisposition), but would rather propose that the lower incidence was a consequence of the method used.

Introduction
Para 2, line 1: "speculation". Speculation it was indeed during a dinner discussion with Archie Brain, the inventor of the LMA, but the wording here has been changed to a more acceptable form:

"Based on theoretical considerations, we hypothesised that the sequence of inflating the cuff and fastening the tube might influence both the seating of the cuff in the surrounding anatomical structures as well as the factors causing airway morbidity".

Para 2, lines 2, (4), 7: The reviewer writes that he does not understand what "fastening" means.

to fasten (= to attach firmly, to affix, to secure) refers to taping the tube of the device to the patient's face and jaw.

We have replaced fastening with fixation and "to fasten" with "to secure" or "to tape" whenever easily possible or feasible.

Patients and methods
Para 1: The patients were randomised the online randomisation program Randomizer® (www.randomizer.org). They were allotted to their groups just
before anaesthesia was induced.

This is important information and has been added to the methods section "To compensate for drop-outs we used two groups of 95 patients each. The randomisation list was created with an online randomisation program (www.randomizer.org)."

Page 6 and elsewhere: "seating of the device".

We used the verb "to seat" in the meaning of "to fix firmly in place" or also "to rest on or fit into another part". The derived noun in question, "seating", means how the LMA rested in or fit into the surrounding structures, i.e. how it was seated. The noun "seat", if used, meant "a part (as a socket) or surface on or in which another part or surface rests" (Merriam-Webster English Dictionary).

This is different from "position" since the latter does not explicitly take the surrounding structures into consideration. It also does not mean "correct placement, position or location", since the LMA could be seated yet still be in an incorrect position.

Since this technical term is so specific we chose to keep it whenever required, seeing that only one of the four reviewers had trouble with it.

Page 7, para 2: When was the LMA removed?

This important piece of information has been added to the methods section: "We removed the LMA when the patient was breathing spontaneously and muscle tone had returned to the jaw".

Statistical analysis:

We used the power calculation module of Statistica (StatSoft) for calculating power and sample size. This information has been added to the methods section.

"All statistical calculations including calculations of power and sample size were performed with the program Statistica® (StatSoft Europe GmbH, Hamburg, Germany)."

Discussion:

We have now placed the description of the study’s limitations in the final paragraph of the discussion.

The reviewer states that the manuscript is quite difficult to read and that it would "benefit from a correction by a native English speaker".

The manuscript was actually written by a native English speaker, who is also an author and editor. We went over it several times and did not find it overly complicated or confusing.

But we have tried to make the text simpler, e.g. by replacing the passive sentences or phrases with a more direct style or using a more commonplace vocabulary.

Reviewer 4 (Gereon Schaelte)
Minor essential revisions:

Introduction
Para 2, line 3: Change requested from "In all published studies ...." to "In most published studies ...."
Although we are not aware of any study in which a different sequence of insertion, inflation and fixation was used, we cannot claim with absolute certainty that none exist. We have therefore written "To the best of our knowledge, in all published studies, the device ....".
The references that we cited are from high impact journals (Anesthesiology, Anaesthesia, British Journal of Anaesthesia etc.)

Patients and methods
Para 1, line 3: "Why didn't you chose the device adjusted to the patient's body weight and height?"
In the last paragraph of the first page of this section we describe clearly why we used a size 4 LMA as the first choice - it fits the majority of the patients. This is also in accordance with the manufacturer's instructions (direct quote "For normal adults, use the size 4 device as a first choice.", LMA, Laryngeal Mask Company, Instructions for use, LMA Supreme®).
Patient weight is not a good indicator for the required size, since the pharyngeal and hypopharyngeal space do not correlate at all well with body weight (a 165cm, 150 kg patient will require the same size as one who is 165 cm and 50 kg, or perhaps even a smaller one). This is reflected by our data; the majority of the patients weighed more than 70kg and would have required a size 5 LMA-S according to one size chart. Only a small minority of the patients actually did require the larger mask (and an even smaller percentage required a size 3).
We have added the reference to the manufacturer's instruction to this paragraph ("... and is also described as the first choice in the manufacturer's instructions for use")

Statistical analysis
As described above, we used the power analysis module of Statistica for calculating the power.

Authors' section
We changed this
Language
"Unfortunately to [sic!] many German phrases have been directly translated without any English customizing ..... strongly recommend a native speaker's or professional re-editing."
The manuscript was written by a native speaker, who has long years of experience in authoring and editing manuscripts, and who was deputy editor-in-chief of an international anaesthesiology journal for over a decade.
However, after living and working in a German-speaking environment for many years, German turns of phrase, Germanisms, are liable to creep in unnoticed. We have gone over the manuscript with great care and changed sentences, phrases and verb tenses that appeared too Germanic.

Sincerely, Dr. Ingo Bergmann, MD