Author’s response to reviews

Title: SupremeTM Laryngeal Mask Airway Use in General Anesthesia for Category 2 and 3 Cesarean Delivery: A Prospective Cohort Study

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Author’s response to reviews:

To: Editor in Chief

BMC Anesthesiology

Dear Editor,

RE: "SupremeTM Laryngeal Mask Airway Use in General Anesthesia for Category 2 and 3 Cesarean Delivery: A Prospective Cohort Study" (BANE-D-17-00156)

Thank you very much for the review of our manuscript entitled “SupremeTM Laryngeal Mask Airway Use in General Anesthesia for Category 2 and 3 Cesarean Delivery: A Prospective Cohort Study” (BANE-D-17-00156).
We appreciate your comments and kind help to improve on the manuscript.

Please find below point-by-point responses to each of the comments (in Italic red font). Amendments to the text are tracked-change in the revised manuscript.

Authorship sequence:

We would like to confirm the authorship sequence.

Shi Yang Li1, Wei Yu Yao1, Yong Jin Yuan2, Wen Shu Tay3, Nian-Lin R Han4, Rehena Sultana5, Pryseley N Assam6, Alex Tiong Heng Sia3,7, Ban Leong Sng3,7

Editor Comments:

This study describes prospective use of 2nd generation SAD for cesarean section. The manuscript may be accepted if the authors respond appropriately on the questions of the reviewers and clarify some points in the manuscript.

They should mainly explain why they have chosen LMA Supreme as their SAD of choice - I understand that its insertion success rate is high and insertion time short, however tracheal intubation through the LMA Supreme in any case of difficulty is not practical.

------- Thank you for your comments.

-------The use of LMA Supreme is the current practice at Quanzhou Women’s and Children’s Hospital. This prospective cohort study examined the use of LMA Supreme in category 2 and 3 Cesarean section where there has not been any large prospective cohort study done before. The previous work on LMA Supreme was done by the same research team, but with less urgent or elective Caesarean section population.

-------The recent Difficult Airway Society- Obstetric Anaesthesia Association has recommended the use of second generation SAD, but does not specifically state the particular SAD to be used. We have put the limitations of tracheal intubation with the LMA Supreme in our Discussion (page 12).
Furthermore, LMA Supreme is quite old SAD of the 2nd generation, its evaluation in cesarean sections has been already performed and possibly randomized controlled comparison with other SAD of the 2nd generation - i-gel, AuraGain, LMA Protector would be more useful. The authors should comment these points in discussion/limitations sections of the manuscript.

------ Thank you for your suggestions.

------ Although LMA Supreme has been in clinical practice for some time, this evaluation would be useful for obstetric anaesthesia practice since most clinicians would have used LMA Supreme in their practice (Ref 16). From our knowledge, there are 3 large prospective cohort studies performed using the LMA classic, LMA ProSeal and LMA Supreme in the obstetric population for Cesarean section. Randomized controlled trials have been conducted to compare various types of 2nd generation SAD, but there is limited work done in general anaesthesia for Cesarean sections. The first randomized controlled trial comparing LMA ProSeal with endotracheal tube for only elective Cesarean section has been performed in only 60 parturients (Ref 29). There are currently no randomised controlled trials published comparing different 2nd generation SAD in emergent Cesarean section. We have added these points in the discussion on future research in obstetric anaesthesia (page 12).

Ron George (Reviewer 1):

1. Within the abstract and other parts of the manuscript when you discuss the use of the double lumen LMA you suggest it reduces the risk of aspiration. I believe this is not a proven fact and only a potential benefit of this double lumen design so in the abstract where you state "hence reducing the risk of aspiration" please consider less definitive language.

------ We have changed to ‘potentially reducing the gastric volume and risk of aspiration’

2. Your introduction is very well written and provides readers with an appropriate degree of background literature. Your hypothesis is based on their being "limited evidence of the use of SLMA in more emergent cesarean deliveries" - however I think you need to offer readers an exclamation of why the previous evidence with a high insertion rate success is not applicable to category two and three cesarean deliveries. Given that category two and three deliveries there is no immediate life-threatening emergency I do not necessarily believe your cohort is significantly different then the cohorts already studied.

------ Thank you for your comments.

------ This cohort study had more emergent indications and included labouring women that could have an increased risk of difficult intubation. Hence, we felt this study would provide clinicians
the evidence-based knowledge of success rate of LMA Supreme insertion during emergent Cesarean section in their clinical practice if tracheal intubation was difficult or failed.

3. Please recall that all pregnant women are in minimum of ASA 2.

------- We have changed to be descriptive. We recruited parturients who are healthy or with well-controlled medical conditions…

4. Please clarify the flow of patients within this project; I want to better understand how you were able to obtain informed consent from every parturient in the antenatal ward or delivery suite. This is quite an accomplishment and I believe other obstetric anesthesia researchers would like to understand and replicate.

------- At Quanzhou Women’s and Children’s Hospital, the investigators (Li, Yao, Yuan) screened and provided patient information sheets and consent of potential subjects at the antenatal wards or delivery suite. If a subject had emergent indication for Cesarean section, the subject would be reconfirmed and recruited into the trial. At this centre, the routine clinical practice would be to use the LMA Supreme as stated in the manuscript (page 4, Methods). This would provide adequate screening, informed consent and recruitment in a pragmatic way for this difficult study design.

5. How did you define gastro-oesophageal reflux disease within your exclusion criteria.

------- Gastro-oesophageal reflux disease was self-reported by paturients. We have added this information in Methods (page 4).

6. How did you define failure of orogastric tube insertion.

------- The successful orogastric tube insertion was confirmed by: a) aspiration of gastric contents; b) injection of air into orogastric tube via the large lumen whilst auscultating the stomach for a “swoosh” indicating gastric placement. Failure to achieve above was defined as “failure of orogastric tube insertion”. We have added the above definition in Methods (page 5)

7. Where are the "additional maneuvers" [chin lift, jaw thrust, head extension] allowed to be used during the primary or initial insertion.
We have included in the Results section that “No additional maneuvers were needed during the insertion attempts” (page 8, Results).

8. What sort of instructions were given to your obstetrician to avoid excessive fundal pressure during fetal extraction.

------ The instructions were “to reduce fundal pressure, to use instrumental delivery such as forceps or vacuum extraction”. We have added these statements in page 6, Methods.

9. On page 6 line 7 you suggest muscle paralysis was reversed, however you only used succinylcholine as described in the methodology. Is this an error or were other muscle relaxants used.

------ We apologise for omitting the details. The attending anaesthetists used rocuronium for maintenance of muscle relaxation. We have added this information in Methods, page 4.

10. I think you should clearly define “consciousness” for when you removed the LMA device.

------ We have included following “Consciousness was defined as when patient was able to follow instructions to open eyes and mouth prior to removal of the LMA device” in page 6, Methods.

11. Regarding your recruitment, what is your institutional cesarean delivery rate and how many women were screened and/or recruited but did not have a cesarean delivery.

------ The Cesarean delivery rate at Quanzhou Women’s and Children’s Hospital is 35% and there are about 2000 women who have Cesarean delivery per year.

In page 4, Methods, we stated that “The investigators obtained informed consent from every parturient in the antenatal ward or delivery suite.” We would apologise for this statement. It should read “The investigators provided information about the study to every parturient in the antenatal ward or delivery suite. If a subject had emergent indication for Cesarean section, the subject would be reconfirmed and recruited into the trial.”

All the women who were recruited had Cesarean delivery.
12. Within the results section, much of the text is simply repeating the data within the tables. You could reduce the amount of text within your results section and use it as an opportunity to highlight the most interesting findings. When adding text to the results section please consider the clinical significance and value added to this section.

------- Thank you for your suggestions. We have revised the Results section accordingly. Please refer to the revised manuscript with track changes.

13. I think you should consider adding an explanation for why you feel peak airway pressure's and negative seal pressure are clinically relevant to this project and why one would expect them to be different between category two and category three caesarean deliveries.

------- We have added the following sentence in Discussion page 11.

“It is interesting that peak airway pressure and peak airway pressure are statistically different between the two groups. However, the clinical relevance is unclear.”

14. You report the results of pH studies of gastric contents and the surface of the element device, is there any evidence to suggest that this difference is not to be expected and has any clinical relevance.

------- The pH on the gastric aspirate and laryngeal surface were similar. We would not expect any clinically relevant differences. We wanted to investigate if there is any possible aspiration.

15. Page 9 line 9 - please correct the sentence "more parturients reported…” As I don't believe the parturients reported this outcome.

------- We have corrected the sentence to “The presence of blood on SLMA was seen more parturients in category 2 (7 (3.6%)) than in category 3 (1 (0.3%)).”

16. Page 11 line 16 - please consider revising this paragraph as you seem to contradict yourself in stating that a limitation was that the majority of parturients were not in labour but in the preceding paragraph you suggest that this is a benefit of this project was the number of labouring parturients.

------- We have removed this sentence portion “Furthermore, the majority of the parturients were not in labour”.

17. Regarding the tables, as I mentioned earlier, the tables should supplement the results section but not be repetitive of all data within the results section. Please take this into account in your revisions.

------ We have revised the Results section accordingly.

18. In the table and within the entire manuscript please include effect sizes were possible including 95% confidence interval's if possible. Simply including "significant" P values unjustly implies a significant outcome where in most cases there were no clinically relevant differences.

------ We have included effect measure and 95% confidence interval in all tables and added relevant methods in page 7.

Souvik Maitra (Reviewer 2):

1. Most important problem is this study is the "low risk patients" selection. Most practical use of second generation LMA in obstetric anaesthesia would be as an emergency rescue device in case of failed intubation. As incidence of failed intubation would be logically higher in patients having predictors of difficult airway, results of this study can not be extrapolated to those patients.

------ We agree on this comment and have put a qualifying statement in the limitations. “The results of this study cannot be extrapolated to patients with difficult airway as most use of LMA devices are in emergency failed intubation situations.” (Page 12)

2. Another limitation is the absence of a controlled group. Probably practicing obstetric anaesthetists would be more interested to know that most suitable second generation LMA in case of failed intubation.

------ The study design was based upon a centre’s routine clinical practice hence it would be a prospective cohort study design. The use of controlled group in failed intubation would be a difficult study to conduct in terms of ethical approval and logistics.

3. A 6% incidence of sore throat in low risk patients actually not very low, and further discussion is required in this area.
We have added following sentences in Discussion, page 11:

“The incidence of sore throat in our study was 6%, which was higher comparing to other studies using LMA Classic or LMA ProSeal (Ref 14, 18). However, it was comparable with our previous study (Ref 16).”

Ross Hofmeyr (Reviewer 3): Thank you for the privilege of reviewing this interesting and important work.

I am of the opinion that the study was well conceived and performed to a good standard.

We appreciate your positive comments.

I note that the entry on clinical trials.gov has not been updated since the registration of the study ion 2013. While this is not necessary for publication, it would be good practice to update the entry to reflect that the study has been completed.

We have updated the entry on clinicaltrials.gov.

The very high insertion success rate is impressive. While I am comfortable to believe that this reflects a high degree of local experience and skill in the practitioners performing the study, it may raise queries. I would suggest making note of the fact that the study population is fairly homogeneous with respect to BMI (due to the selection criteria) and phenotype. Populations with very varied ethnic backgrounds or where selection of the patients for LMA use is less stringent may not have the same results.

We agree with you. We have added the following statements in Discussion (page11).

“Furthermore, the study population was fairly homogeneous in respect to BMI and phenotype, the results may be different from populations with very varied ethnic backgrounds or where selection of the patients for LMA use is less stringent.”

Perhaps worth of discussion is the fact that (put in the discussion) insertion success was very high despite the use of cricoid pressure. Some authors (myself included) advocate release of cricoid pressure on insertion of an LMA, to allow the tip to enter the postcricoid hypoparyngeal space. Your very high insertion success rates (and success of gastric tube insertion) despite
cricoid pressure being maintained call this practice into question, which is very interesting. This might be a feature of the relative rigidity of the SLMA relative to other devices which are softer in the tip (such as the PLMA), and may be of relevance to the reader if the devices used in their centre are different.

------- Thank you for your suggestions. We have added the following statements in Discussion (page11).

“Another noteworthy phenomenon is that insertion success was very high despite the cricoid pressure being maintained. Some anesthetists advocate release of cricoid pressure on insertion of an LMA, to allow the tip to enter the postcricoid hypoparyngeal space. This might be a feature of the relative rigidity of the SLMA compared to other devices which are softer in the tip such as the PLMA.”