Author's response to reviews

Title: The Role of Rigid Indirect Videolaryngoscopy in the Successful Orotracheal Intubation of Adults: A Systematic Review of Randomized and Non-Randomized Trials.

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Version: 3 Date: 20 September 2012

Author's response to reviews: see over
19/20/2012

Dear Sir / Madam,

Please find enclosed our revised manuscript, “An Evidence Based Review of Rigid Indirect Videolaryngoscopy in the Successful Orotracheal Intubation of Adults” by David W Healy et al., which we would like to submit for consideration for publication as a review article in BMC Anesthesiology.

We confirm that this manuscript has not been published elsewhere and is not under consideration by another journal. I have detailed the level of contribution of each author in the manuscript. I confirm that the PRISMA guidelines were reviewed and help guide the development of the review, and reporting in the manuscript. It complies with the PRISMA guidelines. All permissions for the device photographs were sought and approved. I can confirm there are no competing interests, financial or otherwise. All authors have approved the manuscript and agree with its submission to BMC Anesthesiology.

Many thanks to each of the reviewers who took the time to review and provide their thoughtful comments to improve our study and manuscript. We have amended the manuscript extensively to incorporate these suggestions and enclose a point-by-point response to each:

Reviewer: Richard Cooper

The proposed clinical categories are reasonable. I’m not sure if it wouldn’t have been better to look at studies reporting “consecutive patients” rather than “unselected” ones. They may be the same but the latter has a greater potential for reporting bias, always a challenge when evaluating new devices, frequently reported on by enthusiasts.

We agree, we have incorporated this recommendation to our Discussion: future studies section. The term unselected was used in our level of evidence tables to the subject group that were “unselected” based on airway difficulty risk factors, or difficulty encountered on direct laryngoscopy.

Do the authors have any recommendations for future evaluative studies on this emerging technology?

Absolutely. We feel this is the key feature of this review. Our review demonstrates a literature that allows little comparison between devices and therefore weak recommendations to be made. We have added our recommendations for future work based on our review.

I am not convinced that “Rigid Indirect Videolaryngoscopy” adds much to the simpler and more commonly used “Videolaryngoscopy”.

Agreed, we have amended to this term throughout our manuscript.

Suggest modifying the sentence: “When these conditions are not met, for example...the failure rate of conventional direct laryngoscopy increases.” to
“...the failure rate of intubation with conventional direct laryngoscopy increases.”
Agreed, amended.

The use of videolaryngoscopy makes it clear that we must distinguish between seeing the target and successfully inserting the endotracheal tube. It is important to continually reinforce that distinction with precise terminology.
Agreed.

The statement regarding the best available evidence provided by Shiga et al. could be further clarified regarding the patients constituting their denominator. In their meta-analysis, they excluded patients whose airways were “anatomically abnormal” or in whom DL was deemed inappropriate.
Agreed, amended.

Page 5: I would recommend rephrasing the sentence: “However, even given this broad definition of difficult laryngoscopy this still suggests an impressive overall success rate for [intubation by] direct laryngoscopy of over 95%” since laryngoscopy fails if it does not reveal the larynx, even though intubation may be successful. Furthermore, the statement that the standard is high should relate to the population investigated--in this case, patients who were deemed to be suitable for DL. A relatively small proportion of patients would likely have been eliminated because their airways were managed otherwise (bronchoscopically, surgically, retrograde etc.) or intubation was avoided.
Agreed, added text to emphasize this denominator and to put the success into context.

Please confirm that the Storz DCI, V-MAC and C-MAC were regarded as identical devices. This is unclear because the term Storz Macintosh video laryngoscope is used but the company refers to this product as the V-MAC or the Video Macintosh.
Confirmed on p7: The Choice of Devices to study.

Under Data Extraction: would suggest that Number of true difficult laryngoscopy be changed to “Number of difficult direct laryngoscopies (C&L > III)”
Agreed, changed throughout manuscript

Page 10: Difficult Direct Laryngoscopy: this term was used for patients with C/L> III. I prefer the term “Failed Direct Laryngoscopy” because laryngoscopy failed to provide a view of the larynx. Difficult DL is commonly used, but I believe that it is used inappropriately. Please consider rephrasing this. “Failed Direct Laryngoscopy” really should be referred to as “Failed Intubation by DL.”
This is a very interesting point. As a group we desperately need to have agreed definitions of airway intervention findings. We are in agreement with Dr Cooper and the terms he suggests are more accurate than “difficult DL” and “failed DL”. However, currently the term difficult direct laryngoscopy seems to be the most commonly used, and failure implies moving on to do something that is more successful. We worry that using the term “failed DL” to what is commonly considered “difficult” may add confusion.

In the Methods, the authors should explicitly state whether the GlideScope...
Direct, the McGrath MAC or the C-MAC D-blade were included in/exclude from the study. 
*They were included in the initial search, but they did not make inclusion criteria. They were omitted mistakenly for simplification.*

Although one could take exception to the inclusion or exclusion of a wide variety of devices, I’m not clear why the Bullard Laryngoscope was included in this analysis. (It could be argued that if it was included, the search should have included similar devices such as the WuScope and the Upsher Scope, both of which would probably have been subsequently eliminated because of an insufficient number of recent publications.)

*We can confirm this was the case. They were initially mistakenly removed from the original manuscript search for simplicity, but yes, the search was performed for all of these devices – they just didn’t make inclusion based on the criterion of sufficient publications. The Bullard did.*

There appears to be an orphaned * after (until April 2011).
- Corrected, thanks

**:page 8:** First attempt is repeated twice on the last line of Data Extraction.
- Corrected, thanks

Page 9, line 3: separately is misspelled.
- removed, thank you

Maharaj has been misspelled on Table 3 (2nd and 3rd entry).
- corrected, thank you

Page 9, “Other studies have suggested even lower PPVs for the Mallampati score” but only a single study is cited. Suggest including other studies or changing this to “another study”.
- agreed, changed

The paragraph “Evidence for the use of video laryngoscopy in unselected patients” is the perfect place to reinforce the distinction between improvement in rates of successful laryngoscopy and rates of successful intubation.
Agreed, added some clarification to this section, emphasizing this point.

Suggest changing “Evidence for the use of VL in pt assessed to be at high risk of difficult laryngoscopy” to “Evidence...high risk of difficult direct laryngoscopy” and the same for the following sections. Where there are references to “suspected difficult laryngoscopy” and “true difficult laryngoscopy”, these should include the device used (e.g. Direct or even better, Macintosh DL although the latter is often assumed rather than stated).
Agreed, corrected

**Major compulsory revision:**
Page 7: Many of the comments in the paragraph Grading the view at laryngoscopy belong in the Discussion, rather than Methods. “Unfortunately the other grades of of laryngoscopic view[s]…” “the concept of using a full view of the
vocal cords as a desirable outcome measure when comparing direct laryngoscopy...is questionable. These grading schemes are designed and validated for direct laryngoscopy only; however, this measure is used throughout all of the studies as no alternate scheme exists.”

- agreed, moved section correctly to the discussion

Consideration of the Mallampati grade as the sole predictor of a normal or difficult laryngoscopy is both inappropriate and arbitrary a point that the authors themselves state on the following page. I think that Shiga’s paper indicates that Mallampati alone lacks sensitivity and specificity in predicting an adequate laryngeal view by DL, yet more complex scores don’t perform much better. The authors have made a compromise which is justifiable but should be acknowledged as a limitation.

Agreed, added as a limitation. We have expanded that we included cervical spine limitation and obesity as risk factors for difficulty as the authors of these studies (and publishers) assumed that the subjects were at higher risk.

The proposed classification of IVL is reasonable but in the opinion of this reviewer, there is a potential advantage to distinguishing between VL with Macintosh style blades (C-MAC, McGrath MAC, GlideScope Direct) and those with angulated blades (GlideScope, McGrath Series5, Storz D-blade).

Agreed, we have amended the classification to reflect this. Would you like credit in the text for this modification and clarification?

Both the Methods and Results sections contain a good deal of information that more appropriately belongs in the Discussion. The Methods should state what was done (not why) and Results should state their findings, not the reasons for the comparisons, attempts to explain them or conclusions drawn from them.

Moved all the discussion points to the correct position in the discussion.

It is difficult to believe that the performance of these devices was assessed in Appropriately experienced hands. In reviewing the literature, the competency of the operators is rarely stated and the number of prior uses does not adequately address skill level. Furthermore, there is often an assumption that an experienced anesthesiologist or laryngoscopist can be regarded as an experienced operator despite limited familiarity with a different technique. I believe that this is in fact a serious limitation of any such analysis and should be so stated. The same applies to recommendations of how this information should be used. The difference in outcomes relating to experience is highlighted in another study by the authors (26) where the results differed between two institutions involved in a trial.

- added an entire section to the limitations section describing this weakness

Page 16: The comments regarding the description of laryngoscopy/intubation are pertinent not only to VL but all airway maneuvers. It can no longer be assumed that intubation is performed by a Macintosh blade and accordingly, it is important
to always state what devices were used, what view was obtained, what adjuncts were employed and how many attempts were required. Perhaps Adnet’s Intubation Difficulty Score should be advocated. It is probably just as relevant to VL as DL. Terms such as easy and difficult are somewhat subjective. 
- completely agree, standardized definitions are important, we should work toward this as a specialty

Reference 25 has been superseded by reference 13. I don’t think that there is a need to reference both the 1993 (25) and the 2003 (13) Practice Guidelines.
Agreed, removed, thank you

Reviewer's report

Title: The Role of Rigid Indirect Videolaryngoscopy in the Successful Orotracheal Intubation of Adults: A Systematic Review of Randomized and Non-Randomized Trials.

Version: 2 Date: 11 July 2012
Reviewer: Konstantinos Stroumpoulis

Reviewer's report:

Major Compulsory Revisions

Introduction

- thank you, we agree we had jumped to the need for an evidence based review without giving adequate credit in our introduction to the previous descriptive reviews. This is corrected and referenced appropriately now.

Methods

2. Page 7 para 2: The limitation of using such a strict measure of glottic view improvement is the risk missing a lesser, but perhaps clinically significant improvement in glottic view afforded by device use, for instance an improvement from a grade 3 to a 2a view of the glottis. It must be noted that the concept of using a full view of the vocal cords as a desirable outcome measure when comparing direct laryngoscopy with the variety of methods of indirect laryngoscopy is questionable. These grading schemes are designed and validated for direct laryngoscopy only... Hence you did not assess the overall improvement in glottic view described by many studies. Would you suggest that a C/L IV turned into a C/L IIA by IVL does not improve glottic view and therefore does not probably create better conditions for a successful intubation? I am well aware (as the majority of your readers) that a good glottic view does not necessarily equals an easy intubation, on the other hand you are making a long logical jump by accepting that all C/L grades greater than I provide unfavourable
intubating conditions. I am certain that by making this assumption you missed a significant number of clinically significant improvement in glottic views. This constitutes a major limitation of your study. All data is available to you. Can you provide data concerning the performance of each IVL and the comparison between devices? If you have an IVL that converts C/L IV to C/L IIa in a significantly higher rate than the others this is important to know. An evidence-based review would have assessed these differences which are not subtle at all.

- **Completely agree with all points.** If the assessment of C&L was standardized and expressed similarly across the entire body of literature this description of relative improvement would be entirely possible. Additionally, if summary measures of C&L (into easy – I &II, and difficult III & IV) weren’t made this would be possible and desirable. If the C&L was expressed as IIa and IIb this would be helpful too. In this way we could then have examined improvement, which we agree is a clinically useful and important outcome. Unfortunately this was not the case. The C&L is so variably expressed and summarized as to make this relative measure impossible. We did however manage to extract C&L I and we suggest this has some value, but we emphasis throughout the manuscript that this poses significant limitation to any recommendation based on its occurrence. Indeed, it may have resulted in some devices that improved the laryngeal view not being recommended due to lack of evidence. Please see Discussion: The Limitations of this review: Grading the view at laryngoscopy.

- **Following the reviewers excellent advice we have reduced grade view to supplement the success rates**

3. The only measure you included for the prediction of a normal or a difficult airway was the Mallampati score. It is very well known that it has a low predictive validity and that is why other scores have been developed (El Ganzouri multivariate risk index, upper lip bite test etc). By using only Mallampati as a predictive tool you possibly lost some other significant studies focusing on difficult airways such as the following:


- **Thank you for this information and suggestion.** We agree the Mallampati examination is a very poor predictor of difficulty, and we have clarified this on multiple occasions in the manuscript (eg. Please see Discussion – “Predicting Difficult Direct Laryngoscopy”). We are grateful for the reviewer’s advice and suggestions for inclusion of the included studies into the “at higher risk of difficulty” group. Our group did include studies with subjects judged to be at higher risk: such as obesity or cervical spine limitation. Unfortunately, we considered the Marrel et al (2007) article but it failed criteria for inclusion as the device under study was the “Rusch or X-Lite videolaryngoscope”. The study by Stroumpoulis et al. was unfortunately missed in the initial search as the authors used the term “videolaryngoscopy” in the title rather than the actual device under study ie. the “GlideScope”. This was a mistake as we completely agree that this study adds extra information to the evidence for the use of the Glidescope in true difficult laryngoscopy. This has been added and entered as an additional paper into all the review following the accepted methodology. Stroumpoulis and colleagues must be commended on the methodology employed to accurately discover the incidence of true difficult laryngoscopy (C&L III and IV) in the study group. However, the overall methodological quality score did suffer from lack of randomization and blinding.
4. On the other hand, you have included several manikin studies. Despite manikin studies may form an attractive choice for investigators for a number of reasons, particularly with respect to obviating the need for careful patient selection and recruitment, but also in terms of proving a safe, standardized and reproducible environment that will likely yield reliable and comparable data, several concerns are raised with the growing number of studies that are initially assessing airway management devices in a simulated setting and argue that many of the aforementioned reasons limit the degree to which finding generated are applicable and generalizable to human populations


Therefore there is a high probability that your sample is highly heterogeneous and your results not something that one could say representative. Please add this observation to your limitations section.

- disagree; our inclusion criteria excluded all manikin studies. We agree that if we had included them our sample would be extremely heterogeneous with limited relevance to a clinical population. We decided to limit our review to human studies.

1. Page 4 para2: Indirect videolaryngoscopy (IVL) is a recent development. I would not characterize as a recent development a device that has been developed more than 10 years ago. Please rephrase.

- thank you, rephrased

2. Page 4 para2: This may be incorrect as an improvement in success may be limited by both use of unfamiliar equipment….please rephrase: unfamiliarity with equipment and difficulty in advancing the ETT. and difficulty placing an endotracheal tube out of the line of sight. However, this is not the case in IVLs since the ETT is placed under continuous direct vision (as all manufacturers suggest). I wonder whether the authors have ever used any of these devices. Please erase this comment.

- disagree, respectfully we think the reviewer misunderstands our statement. The “line of sight” is commonly held to indicate “the line made between the operators eye and the target”. This is a key feature of direct laryngoscopy as the “target” (the glottis) is visualized under direct vision. Indirect laryngoscopy involves a projection of the image of the target (the glottis) onto some kind of representation, in the case of videolaryngoscopy: a video monitor. This can be out of the “line of sight” and therefore visualization occurs indirectly. I would assume that the manufacturers suggest that the ETT is placed “under continuous indirect vision”. This may lead to a failure of intubation (despite a perfect indirect view of the glottis on a video representation) if the operator is not skilled in manipulating an endotracheal tube “out of the line of sight”.

- As an aside, I can reassure the reviewer that the authors have experience of these videolaryngoscopic devices in clinical practice.

4. Page 5: as many patients can easily be intubated blindly…do you mean by conventional means? (with a bougie, an ILMA, a fastrach etc?). Please elaborate.
agreed, blindly is not a useful term here, we have clarified this to specify the use of a gum elastic bougie

5. The evidence for efficacy…
there are no accepted or published success rates of direct laryngoscopy…
I beg to differ. There are studies. See my previous comment on the studies by Stroumpoulis and Marrel.
Thank you, we rephrased this to be less absolute

6. Of note, the evidence for the GlideScope is limited to a small study where the view was improved to a Cormack and Lehane view 1 in only 8% (4 patients).
I beg to differ.
Please search the literature a little more! See the studies by Stroumpoulis and Marrel. Please also consult the following study: Rope TC, Loughnan BA, Vaughan DJ. Videolaryngoscopy: an answer to difficult laryngoscopy? Eur J Anaesthesiology 2008; 25:434-435.
Again, we completely agree regarding the Stroumpoulis et al. (2009) as this has now been added to the evidence for this group, however, the Rope correspondence and Marrel study are the only ones examining the X-Lite device, and as such did not achieve the minimum inclusion criteria.

7. Discussion
Please relate your evidence with other relevant reviews.
We have referenced the other reviews and added their findings to the text. The main review that performed some version of qualitative assessment was the Mihai study, the others used individual studies to illustrate the authors points – so didn’t have the same kind of findings as our current systematic review, so it was hard to use them to confirm the current findings.

Please comment more on your findings.
We have added additional text to the findings to give extra context and draw attention to the limitations. We have added a great deal more comment and context.

8. Overall comments
I believe that the use of the terms “recommend”, “recommendation” is rather strong especially when it is not coming from an executive committee or a working group. Please consider using another term.

Following the reviewers advice we took a close look at the entire methodology to see if we could give more context and value to the recommendations. We re-assessed all the articles and evidence charts, and agreed that the chosen methodology would allow us to broaden and weaken our recommendations to include more devices with weaker levels of evidence and subsequent weaker recommendations. We are very grateful to the reviewer for allowing us to provide more information and qualification to the current review. Our recommendations are now qualified by reservations and limitations throughout the article. The methodology allows a grading of recommendation from weak to strong. A recommendation made by 4 academic anesthesiologists after performing a systematic review according to standardized assessment of quality has less weight than that provided by a national or international working group. But we would hope that our work would go some way to make that working groups work easier.

9. Please include the aforementioned limitations throughout my comments to the appropriate parts of your limitations section.
We appreciate the thoughtful comments, and have addressed many in the limitations section.

Reviewer's report
Title: The Role of Rigid Indirect Videolaryngoscopy in the Successful Orotracheal Intubation of Adults: A Systematic Review of Randomized and Non-Randomized Trials.
Version: 2 Date: 11 July 2012
Reviewer: Jochen Hinkelbein

P4 L23: incidence of difficult intubation does not only depend on definition and patient selection, one of the most important aspects is experience of the laryngoscopist (e.g. first year trainee vs several years of experience in ENT anaesthesia). There is much recent literature on this topic, please include and clarify this important point.
Agreed, corrected, please see Discussion: Limitations of this review: 4. Operator performance and competency.

P6 exclusion criteria.
You have excluded manikin studies without further discussing this.
On the one hand, it is desirable to use only data gathered from studies performed with humans, since the airways from manikins are still far away from reality. On the other hand, due to the enormous variations of the human anatomy, and the enormous variations being created by using different drugs and doses for intubation (especially when thinking of stepping back to spontaneous breathing in case of expected difficult intubation), the manikin provides the only standardized and thus non-biased “airway” for comparing different devices. When excluding manikin studies, these problems have to be discussed.
There has been a significant amount of recent discussion in the literature regarding the applicability of manikin studies to clinical practice. This is a systematic review of clinical efficacy of videolaryngoscopy. Indeed one of the other reviewers mistakenly thought we had included manikin studies and criticized us for this inclusion. We feel the use of manikin studies is really not appropriate to a review of clinical efficacy.

P7 grading view at laryngoscopy
Please make this paragraph shorter and more concise. The grade of view is not as substantial as in direct laryngoscopy, and of limited significance for intubation success – a good indirect view does not guarantee easy and successful intubation. As you correctly state later in the discussion, the C/L grading is not useful for video laryngoscopes, and an alternative grading should be used in future.
P8
MP - Please give explanations for all abbreviations at their first use.
P9 L3 separately
P12 L1
Time to glottic view is often described, but more or less only of academic interest when comparing video laryngoscopes, because a good view of the glottis does not necessarily mean that endotracheal intubation can be performed easily and quickly as in direct laryngoscopy. Intubation success alone doesn’t make a good endpoint either. Especially when bag-mask-ventilation is difficult or not wanted
(rapid sequence induction), time to intubation is the time that matters clinically. Please emphasize this.

Time to intubation is important and we have added this to the text. It just isn’t measured well, presented, or analyzed well in the literature and makes comparison impossible.

L22: The recommendation to use video laryngoscopes to achieve a higher percentage of C/L I scores is questionable. You state yourself that the Cormack/Lehane classification is a useless classification for video laryngoscopes. Besides, a C/L I is not essential for endotracheal intubation. Following the reviewers comments, we have reduced this outcome to be of supplementary importance in our review and recommendations. We have clearly stated that this high standard limits the variety of devices in the recommendations if it was used as the sole determinant of a recommendation and have now clearly stated that it is supplementary to overall success.

P13 L9: Again, there is no need for a C/L grade I view, as long as the glottic structures can be securely identified and the tracheal tube can be inserted successfully and timely. I do not think that these strong recommendations can be made when not considering time needed for successful intubation. We understand the reviewers comment and reservations, we have reassessed the entire evidence base and formulated a wider set of recommendations based on, and clearly marked as so, reduced levels of evidence. This has allowed us to add other devices that have a more limited evidence base for their use – but this is clearly stated with reduced level of evidence. When taken in context of the objective grading system and constant reference to the limitations these are simply recommendations based on an objective systematic appraisal of the limited, poor quality evidence in existence.

P14: With only retrospective data available, the strong recommendation for a specific device should be weakened. Agreed, based on the feedback of the reviewer the entire assessment was repeated and classified accordingly leading to a greatly reduced grade of recommendation. We are delighted to have the opportunity to correct our findings and are very grateful for the reviewers comment and opinion.

Forest plots of your results – e.g. one for each group – would be desirable to have a better overview of the results. Forest plots would be nice as a visual representation of some of the information, but would duplicate the findings in the tables. We have added an additional figure to help illustrate the overall evidence.

P15: You state that devices were used by appropriately experienced users. Did you check that for each study included? How do you define appropriate experience? (See Bernhard et al, developing the skills of endotracheal intubation, AAS 2012) Experience of the user is of outstanding importance and should be discussed. I do not believe that it can be stated that all users of the video laryngoscopes were “appropriately experienced”. Completely agree, added a section specifically focused on this limitation/weakness and combined it into the section regarding future investigations.

Conclusion: As stated earlier, please weaken your strong recommendations for specific devices.
Thank you, this has been changed by repeating the entire review and repeat classification. Recommendations are now completely in line with the objective criteria.

Thank you for your consideration,
Yours Sincerely,
David

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