Title: Comparison of the Glidescope, flexible fibreoptic intubating bronchoscope, iPhone modified bronchoscope, and the Macintosh laryngoscope in normal and difficult airways: A manikin study.

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Version: 2 Date: 2 January 2014

Author's response to reviews: see over
2nd January 2014

Dear Editor

I thank the reviewers for their comments and have tried to address these and provide additional information where required.

I have also corrected the formatting of the article and included the name of the local Ethics committee.

We look forward to your response.

Sincerely

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Editor's Comment:

Reviewer's report ? rev. No. 1:

**Major Compulsory Revisions**

The study goal remains unclear. Was it to show feasibility to use a smartphone as a screen on a fiberoptic bronchoscope? That's hardly worth a study. Was it to show there is no relevant time difference between fiberoptic with a smartphone screen vs. no screen? Then why should the anesthetist bother using a smartphone? It would have been different if the authors had tried to show how the smartphone was a useful teaching device in case there is no other screen around.

The reviewer has correctly deduced the reason for the study, namely we tried to show how the smartphone could be useful as a teaching device in the absence of a screen. We have 8 theatres, 2 laparoscopic stacks, both of which are used by the surgeons, and no equipment to enable us to connect the bronchoscope to those stacks. Teaching fiberoptic bronchoscopy is difficulty with junior registrars when looking through an eye piece. I work at another facility which has a dedicated video bronchoscopy stack, which is more useful for teaching and performing procedures (such as removing food boluses). We obtained a quote to buy a dedicated anaesthetic bronchoscopy stack; however this was prohibitively expensive for our department. The iPhone apparatus seemed like a simple and inexpensive (~ $60 AUD) idea but ultimately did not compare well with our current equipment but was useful for teaching technique and anatomy, as outlined on page 12 of the discussion. Most participants said they would be happy to use the device if it were available for clinical use when a fiberoptic intubation was required.

I have added ‘where a screen for video-assisted bronchoscopy was not available.

The last sentence in the Background section remains completely unclear. What are ?non medical anesthetic personnel?", and how should recruiting those account for variables that may influence performance?

Since our study examined the level of operator experience on time to view the vocal cords and time to successful intubation we included the anaesthetic nurses as a ‘control group’ to account for variables other than intubation technique that we may not have considered. All participants were given the same instructions and opportunity to practice intubating the manikin as outlined in the methods section. Many studies use novice groups including nurses, paramedics, medical students, respiratory therapists in their protocols [1-4]. The nurses were inexperienced with using the Glidescope but had no failed intubations. Our results with the Video-laryngoscope are consistent with other published studies in this respect. Hodzovic et al used senior house officers with little or no experience with any of the devices in their manikin study assessing the effect of operator experience on fiberoptic intubation through different airway conduits [5].

Although video-assisted instruction may improve intubation success when teaching fiberoptic intubation it did not make a significant difference with the iPhone attached. Despite our results interest in this technology is growing. Since this study was conducted there has been
an iPhone app released (iLarynx – fiberoptic laryngoscopy simulator) and correspondence published outlining how to use an iPad to assist fibreoptic intubation. http://www.respond2articles.com/ANA/forums/thread/1240.aspx

The sample size calculations remain unclear. First, one of the study mentioned (reference 7) showed results in patients, not manikins. Second, it remains unclear why 20 seconds should be clinically meaningful. Third, the method to calculate the sample size should be mentioned.

We have tried to make our study as similar to previous published studies as possible. A description of the sample size has previously been published [5]. We were able to demonstrate significant differences in our end points suggesting our study was adequately powered. I reviewed patient studies to ensure our time frames were reasonable as there were a limited number of manikin studies using fibreoptic intubation. No point in taking longer to intubate a manikin than a real patient [6].

The discussion is unnecessarily long and can easily be shortened by half.

I have tried to shorten where possible.

The conclusions are not supported by the study and should be re-written. The only conclusion that can be drawn is the fact that performance with the iphone device was similar to the standard fiberoptic device.

Respectfully disagree. I think this study demonstrates that a relatively cheap could be an invaluable asset to smaller departments that lack access to video-assisted bronchoscopy. I also believe this study highlights the increasing use of video-laryngoscopes to the detriment of fibreoptic skills. The study also confirms previously published data demonstrating the ease of use of video-laryngoscopes by novice users with little training.

The figures are not helpful to understand the study results. Fig 3 C and D are unclear? is this the mean of all devices? Shouldn?t they graphs rather show the difference of the devices in both scenarios?

I presented the data in a similar way to previously published reports [1, 3, 7].

Minor Essential Revisions
The second sentence and the last sentence in the abstract (conclusion) are not supported by the data and should be omitted.

Respectfully disagree. I believe this study has ‘suggested’ this result and would be worth investigating further. Our college (ANZCA) has now implemented a volume of practice requirement to training. I think many registrars may struggle to reach these requirements given the increasing popularity of the videolaryngoscopes.
Usually, only one primary endpoint is given. In this case, time to intubate. All other endpoints are secondary endpoints. Some minor editing are necessary (e.g. ?consultant anaesthesist?

Multiple primary endpoints have been listed in the studies I have previously discussed. An endpoint is an entity of interest in a trial. Since this trial assessed intubation times with different tools is it entirely reasonable to include time to view vocal cords, time to successful intubation and failure of those tools as primary endpoints of interest.
Reviewer's report ? rev. No. 2

Major Compulsory Revisions

Background
(page 4, lines 3-4): please clarify role of fiberoptic intubation as rescue device in failed intubation, with special reference to avoid its use in case of asphyctic emergency.

Have clarified the role with reference to the ASA Difficult airway algorithm where Fibreoptic intubation can be considered when face mask ventilation is adequate.

(page 4, line 6): better to refere performance of videolaryngoscopes to better view of vocal cords and larynx, rather than to epiglottis.

I have altered epiglottis to replaced it with glottis to better reflect the terms used in other papers and reviews [8].

(page 4, line 10): there can be different reasons of videolaryngoscopes failure, not only restricted mouth opening, such as, for example, active bleeding or difficulty to address tube. So it could be better to write ..might fail for different reasons, for example if there is difficulty..?

Have broadened reasons for videolaryngoscope failure.

(page 5, line 3): better specify iPhone producer/manufacturer, exactly as with all other devices mentioned in the text (i.e. Apple Inc, Cupertino, CA, USA..)

Have updated this.

Results
(page 9) I would recommend adding some comment on great difference with experience of devices within groups, just to make it clearer different performance reasons. In example, nurses did not have any experience with fiberoptic, and this explains statistical results, while, especially if not clarified, could be bias source for some conclusions.

On page 5 of the background I outlined the reason for recruiting non medical anaesthetic personnel mentioning level of experience. In the discussion (page 13) I have briefly mentioned why I think there is a difference between the consultant and registrars. The nurses overall experience and demongraphics are listed in Table 1.

Discussion
(page 11)
i suggest to provide some temptative explanations for low performance of iphone if compared to conventional fiberoptic+video, maybe citing technical problems
elsewhere described and focusing on visual limitation (iphone camera resolution lower of conventional CCD camera devices!) and screen dimensions.

Have added to the discussion. Tried to limit this to discussion between the Glidescope and iPhone as compared in the study. They both have similar resolutions; Glidescope VGA 640 x 480 pixel and iPhone 4 640 x 960 pixels. Although the iPhone image was smaller the camera function allowed you to zoom in and out which was useful if you lost your orientation.

Reason for lower performance within nurses could be also their basic lack of experience with conventional fiberoptic. In fact, adding external screen to substitute direct eyepiece vision, adds further coordination difficulties, and might perform better if a basic fiberoptic skill is already acquired.

Many nurses indicated that they would have liked more time to play with the manikin and the intubation devices. All participants were treated equally and given the same instructions and opportunity to practice with the equipment as outlined in the methods. Unfortunately, apart from participating in this study our nurses are not allowed by management to use the fiberoptic equipment as it is deem ‘beyond their scope of clinical practice’.

**Conclusions:**
i would recommend to make it clearer, with special reference to suggested

Thankyou for your comments.
Reviewer's report ? rev. No. 3:
Overall this is interesting and well conducted study within its limitations that are clearly stated. Methods used are appropriate and well described. Concept of using iphone connected to bronchoscope is new and original. Unfortunately study showed that exiting design of iphone connected directly to bronchoscope wasn?t really ergonomic. This is correctly highlighted in very thorough discussion.

Authors suggest that using iphone for wifi streaming to ipad would be better. Also comparison of this configuration to bronchoscope with viewfinder and bronchoscope connected to video stack would be more clinically relevant.

Minor Essential Revisions:
1. In conclusion paragraph page3: ?Results obtained in manikin studies can often not be directly extrapolated into clinical practice.? It should be stated clearly without hesitation that these results cannot be extrapolated into clinical practice to avoid misinterpretation. As it was mentioned already in many studies and very well discussed by Minai R. et al in their paper

(1):? We are not aware of any substantial evidence that manikin studies correlate with clinical performance in this area. The use of rigid plastics, the lack of collapsible soft tissues, absence of secretions and the fact many manikins do not have anatomically correct epiglottic and laryngeal structures makes them very unlikely to be useful surrogates for evaluation of either easy or difficult intubation. We recently evaluated four modern manikin in several domains of airway management. Based on this, we would conclude that intubation is not reliably simulated by manikins.?

I agree with Mihai et al [9]. The authors in the study raise a valid point that intubation is not reliably simulated by the use of manikins. Airway manikin simulators have been around since the 1950s and are invaluable tool in medical education. These manikins provide a safe environment to practice new technologies and practical skills, avoiding danger to the patient. Training with high fidelity simulators improves knowledge and consolidates technical skills. Whilst there is limited evidence that manikin studies correlate with clinical performance they are widely used in research and education. A PubMed search using the terms “airway manikin” and “intubation” yielded 31 studies between 2006 and 2013, many published in the journal “Anaestheisa”. I have updated the sentence the included the reference discussed by the reviewer.

2. In results page 9: ?Time to view the cords (TVC) and Time to successful intubation (TSI) verses device?. Is verses misprint? It occurs again in: ?Time to view the cords and Time to successful intubation verses operator experience...? 

Thankyou for picking this up. Both have been corrected.
3. In discussion page 13: ?The results may have been different if a smaller size or (?) brand of ETT was used...?

I have re-checked the brand of ETT used and it was Portex, not Mallinckrodt. I work at a few facilities and erroneously wrote Mallinckrodt instead of Portex. We also stock a few Parker Flex Tip Endotracheal tubes. The Parker Flex Tip has a flexible, curved, centered, tapered distal tip geometry that is designed to facilitate rapid, easy, non-traumatic intubation. The first pass success rate for advancing a Parker ETT into the trachea during oral fiberoptic-guided intubation is significantly higher compared to a standard ETT in neutral orientation (71% vs 11%, respectively) [10]. I have used both and found the Parker Flex Tip ETT does help but it is not the standard ETT used within the department. Part of the problem with the portex ETT was railroading it through the cords, as can occur in real life. We used the manikin lubricant prior to each attempt as per the manufacturer’s instruction (MegaCode Kelly Manual). We may have recorded different times for successful intubation attempts with the Parker-Flex compared to the standard Portex ETT. We only stock even size endotracheal tube sizes. Females commonly get a size 7 and Males size 8mm ETT. (The manufacturer recommends a size 7.5mm ETT for MegaCode Kelly). A few authors have used smaller ETT in their studies. A size 7 ETT was used by Healy et al in an AirSim Advance (Trucorp Pty Ltd, Belfast, UK). The manufacturer recommends a size 8-9mm for oral intubation [7]. Similarly, Burdett et al used a size 7 ETT in a SimMan Manikin (Manufacturer recommends size 7.5 ETT) [11].

AIRSIM LINK
http://www.trucorp.com/products/airsim/advance-larynx/

SimMan Manual

4. Figure 3 page 18: There is incorrect description in table and figures: ?Boxplots demonstrating the effect experience of the operator and intubation difficulty on time to view the vocal cords (A and B) ? should be (A and C) and time to successful intubation (C and D) ? should be (B and D)?

Thankyou for picking this up. No matter how many times I read this manuscript I still find errors!

Discretionary Revisions:
1. In defining secondary outcomes the ?user rated degree of device difficulty? sounds quite cumbersome.

Have changed this to user rated device difficulty.
2. Ad conclusion: I would suggest to consider rewording: ?the combination of smart phone technology and fiberoptics may provide a novel and relatively inexpensive method of teaching this essential skill? - I don?t think it provides different method, you?ll get the same with AMBU?¢s aScope3 or intubating bronchoscope connected to video stack but you are definitely getting alternative device (configuration) that can facilitate this method of teaching.

Have changed the word novel to alternate as suggested.

3. It would be useful to add picture of vocal cords done by iphone through bronchoscope to illustrate picture quality and also picture of operator using iPMFB on manikin to demonstrate how (non-) ergonomic this configuration was.

I have included a picture of the vocal cords through both the Glidescope and iPhone. I have photographed the setup used (Figure 1); However, I did not seek ethics approval to photograph participants, or trial investigators, whilst performing the fibreoptic intubation study. The ethics committee has set meeting dates and given it is the holiday season I regret that I will not have sufficient time to discuss this with the committee before the re-submission date of Jan 2nd. The original ethics application took nearly 2 months to approve, despite being a low risk study. Picture of vocal cords is now Figure 2.

4. Ad Tab 1: For estimated number of FO intubations there is median of 0 and range (0-12) for registrars. How many of them had any previous experience with FO intubation?

Ad Fig 4: Does this mean that there were 6 times more failed bronchoscope intubations and failed iPMFB by consultants than failed FO intubation by registrars? If this is the case it is very interesting and worrying that registrars with no exposure and experience performed much better in FO intubation than consultants, it would probably warrant some more comments in discussion.

In regards to previous FO intubations the question asked was how many FO intubations have you previously performed by on patients? 8 registrars had had previous FO experience with patients. 3 of these reported performing > 10 FO intubations. We did not ask how many FO they had previously performed on manikins or airway simulators. The bronchoscope used was a dedicated teaching bronchoscope, so the new one was not broken. I know some of these registrars may have had previous experience with bronchoscopes and manikins at other hospitals that they had rotated through as part of their training. I included the nurses in the study as a ‘control group’; none of these had had prior experience performing FO intubations themselves on patients or the manikin.

With the normal bronchoscope there were 4 failed intubations in the normal airway and 2 in the difficult airway for the consultants whereas the registrars had none. There were more failed intubations with the iPhone for the consultants compared to the registrar group. I have tried to address this result in the discussion on page 13. This may be related to the facility where the study was conducted. The study was undertaken in an urban facility located
approximately 20 minutes from a large tertiary hospital with several hundred beds. Many of the consultants had been at the urban hospital for many years and with the current case mix the opportunity to perform awake fibreoptic intubations was limited. During the 6 month period I undertook this study I can recall 3 awake FO intubations being performed in OT, that I am aware of. I did 2 of them. The registrars are a mixture of either basic trainees or more senior trainees who have almost finished their training. I know several of these had attended intubation workshops and had played with fibreoptic bronchoscopes as part of their training at our tertiary facility. I alluded to this in my comments stating that the results may have been different if I had performed this at the tertiary centre where FO intubation is done on an almost daily basis. Several of the older consultants I spoke with had not performed an awake FO intubation in years. Although some of the registrars had had previously limited experience with the scopes their learning curve appeared to be much shorter. It may have been interesting to record how many of them played online games (ie Playstation etc.). The anaesthetic college (ANZCA) has now adopted a volume of practice requirement in the curriculum along with a dedicated clinical log book. It would be interesting to see in a few years the volumes of awake FO intubations being performed; As stated in my conclusion I suspect that videolaryngoscopy will play a greater role in difficulty in the future.

5. When comparing Macintosh blade used dor DL intubation failure rate it would be also interesting to report Cormack and Lehane grade if it is available.

Sorry, we did not record this data.

According to methods there wasn?t gum elastic bougie or stylet used to facilitate DL intubation. Stylet was apparently used to facilitate intubation with Glidescope. What was reason for exclusion this common equipment used for patients with difficult laryngoscopy? Why authors opted for size 4 Macintosh blade? Is it blade recommended by manikin manufacturer?

According manikin?s manual there is recommendation for LMA size 4 and ETT 7.5, I would expect that manikin is size of medium adult. In that case size 3 Macintosh would be more appropriate to use to improve tracheal intubation success. Could you please comment on this?

It is common practice in our department to use the rigid stylet with the Glidescope. The GlideScope videolaryngoscope usually provides excellent glottic visualization, but directing an endotracheal tube (ETT) through the vocal cords can be challenging. This is consistent with the described methodology in similar studies [1, 3]. All participants were treated equally and used the same equipment. I am aware that some studies allow for the use of a gum elastic bougie [11]. Only two consultant anaesthetists failed to intubate the manikin in the difficult airway scenario so I would argue that stylets and bougies were probably not necessary.

A size 4 Mac blade is the most commonly used blade in our department. There are no specific Laryngoscopes blade size detailed in the MegaCode Kelly manual, that I am aware of. In some of the studies referenced above a size 4 metal blade was also used.
REFERENCES


