The use of an anaesthetic simulator to assess single-use laryngoscopy equipment

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Abstract

Objective. To compare the view at simulated direct laryngoscopy obtained with a standard laryngoscope, with and without a disposable cover and a disposable laryngoscope blade.

Design. Randomized non-blinded comparison.

Setting. The high-fidelity human patient simulator at the Scottish Clinical Simulation Centre.

Participants. Thirty-two anaesthetists with between 11 months and 25 years of experience.

Interventions. A randomized comparison of ease of laryngoscopy with each laryngoscope option for simulated easy and difficult laryngoscopy.

Main outcome measures. The best grade achievable at laryngoscopy (Cormack and Lehane grade) for each laryngoscope, for both easy and difficult laryngoscopy.

Results. For the easy setting, 34% (P = 0.001) of anaesthetists graded laryngoscopy more difficult with the covered laryngoscope, and 22% (P = 0.008) with the disposable laryngoscope considered laryngoscopy more difficult than with the standard laryngoscope. For the difficult simulator setting, 69% (P < 0.001) found laryngoscopy more difficult with the covered laryngoscope and 69% (P < 0.001) with the disposable laryngoscope, when compared with the standard laryngoscope. There was no difference between the laryngoscopy grades for the covered and disposable laryngoscope for either easy (P = 0.21) or difficult (P = 0.87) simulation.

Conclusions. Single-use equipment, as presently recommended for tonsillectomy surgery by the UK Department of Health, makes laryngoscopy more difficult for anaesthetists.

Keywords: Creutzfeldt–Jacob disease, laryngoscope, laryngoscopy, patient simulation

In 2001, the Department of Health in the United Kingdom recommended that all tonsillectomies should be performed with disposable equipment to minimize the risk of prion transmission [1]. This was despite the risk of prion transmission in relation to the use of surgical or anaesthetic equipment being unknown [2,3], and the acknowledgement that the change in practice might, itself, pose different risks [3].

For anaesthesia, this advice was interpreted by the Royal College of Anaesthetists as relating to both surgical instruments and anaesthetic equipment. In particular, it was recommended that if laryngoscopy was to be performed that disposable blade covers or disposable laryngoscope blades should be used [4]. However, following this change in practice there were anecdotal reports of anaesthetic and surgical difficulties with disposable equipment [5–8]. This raised the possibility that there may be a safety issue in changing practice, prompting the Department of Health and, subsequently, the Royal College of Anaesthetists to withdraw this advice [9,10].

To add to the confusion, after 4 months and further discussion with the Department of Health, the Royal College of Anaesthetists reinstated the recommendations [11]. The wisdom of this U-turn has recently been called into question [12].

The only way to be certain of no risk of cross transmission of infection is to use disposable laryngoscope blades or disposable covers for laryngoscope blades. However, little is known about the effect of an enforced change of laryngoscopy practice on the incidence of difficult or failed intubation. In contrast to the theoretical risk of transmission of new variant Creutzfeldt–Jacob disease (vCJD), difficult tracheal intubation continues to be a relatively frequent problem [13] and is associated with significant morbidity and mortality [14]. Other authors have used an anesthetic simulator in a partially randomized manner and found laryngoscopy more difficult with single-use equipment [15]. A worse view at laryngoscopy has been associated with an increased incidence of difficult or failed intubation [16].

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Therefore, we have designed a fully randomized study to compare the view obtained at laryngoscopy between standard and disposable equipment using a high-fidelity human patient simulator.

Methods

Study population and setting

Thirty-two anaesthetists were prospectively recruited while attending or teaching on courses in the Scottish Clinical Simulation Centre. All anaesthetists were given the opportunity to decline participation in the study. They were familiarized with the clinical simulator (modified Model C simulator, Medical Education Technologies Inc. Sarasota, Florida, USA) and with the Cormack and Lehane laryngoscopic grading system (Table 1). This model of simulator can provide a range of intubating conditions from normal (easy) to impossible. The simulator was run for all participants in a standard setting for normal (easy) intubation. The ‘difficult’ intubation setting was achieved with this simulator by setting the tongue swelling option to ‘swollen’.

Study design

Anaesthetists were asked to compare three laryngoscopes (Figure 1): (i) a standard, stainless steel, Macintosh type, size three laryngoscope; (ii) the same standard laryngoscope with a disposable blade cover applied (LaryGard™ size 3, Penlon Abingdon, UK); and (iii) a disposable, Macintosh type, size three laryngoscope blade (Crystal™, Penlon). All laryngoscopes were fitted with new batteries at the start of each session. All disposable blades and blade covers were new for each anaesthetist’s attempts (in case their performance would deteriorate with multiple uses).

Anaesthetists performed laryngoscopy with each of the three laryngoscopes in both the easy and difficult intubation settings. They could not be blinded to the laryngoscope they were using to view the larynx of the simulator model. However, they were sequentially allocated a study number in the order they participated in the study. The order they performed laryngoscopy with each possible permutation of laryngoscope and difficulty setting was randomized by allocation from random number tables performed in advance by a non-observer. In effect, each anaesthetist was given each laryngoscope in a random order; also, they did not know whether the intubation difficulty was set to easy or difficult. The participants were asked to perform laryngoscopy as they would normally do, specifically, they were allowed to use laryngeal or cricoid pressure to improve their view if they desired. The best view they obtained at laryngoscopy was recorded. For this, they used a 4-point scale popularized by Cormack and Lehane [17], with which they had been previously familiarized (Table 1). In this scale, a higher score indicates a worse view of the larynx.

Statistical analysis

Laryngoscopic grading was compared for the same anaesthetist for each laryngoscope in each difficulty setting. Data were paired, ordinal, and non-parametric; consequently, comparisons were made by Friedman analysis of variance by ranks. Post hoc tests were performed with Wilcoxon Signed Ranks test. The relationship between anaesthetic experience and laryngoscopic grading were examined using Spearman’s rank correlation coefficient for all laryngoscope-/simulator-setting combinations. All data were analysed using SPSS 10.0 for Windows. We were unaware of any studies defining the scatter of laryngoscopic grading by anaesthetists using an anaesthetic stimulator. Therefore, we performed a retrospective power calculation using the highest standard deviation (SD = 1.0) of laryngoscopic grading for the covered laryngoscope on the difficult setting for all 32 participants. This suggested that the study had power of 0.92 at the 0.05 significance level and 0.80 at the 0.01 significance level.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Cormack and Lehane grading of laryngoscopy [17]</th>
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<tbody>
<tr>
<td>Grade</td>
<td>Description of the best view obtained at laryngoscopy</td>
</tr>
<tr>
<td>Grade 1</td>
<td>Epiglottis and most of the glottis are visible, i.e. vocal cords and arytenoids</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Epiglottis and only the posterior extremity of the glottis, i.e. the arytenoids are visible</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Only epiglottis is visible, i.e. none of arytenoids or vocal cords is seen</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Not even the epiglottis is visible</td>
</tr>
</tbody>
</table>

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Figure 1 The laryngoscope options used in the study. All options used the same laryngoscope handle and battery source. Option 1, standard Macintosh size 3 laryngoscope; option 2, plastic ‘LaryGard™’ blade cover placed over option 1; option 3, plastic ‘Crystal™’ disposable blade Macintosh size 3.
Results

Summary of the laryngoscopy grades found by the group of anaesthetists as a whole for each combination of easy or difficult simulator setting and each laryngoscope are shown in Figure 2.

All summary data are expressed as median (range).

Validation of difficulty setting

Firstly, we considered the ability of the simulator to mimic a more difficult laryngoscopy grade using the standard MAC3 laryngoscope. From Figure 1, it can be observed that the grade at laryngoscopy was higher for 20 of the 32 participants (62%). The median laryngoscopy grade was 2 (1–3), for the difficult setting (difficult/standard), when compared with the easy setting (easy/standard), laryngoscopy grade 1 (1). This was statistically significant ($P < 0.001$).

Effect of laryngoscopy equipment

Changing laryngoscopy equipment had a significant effect on the laryngoscopic grade for both the easy setting ($P = 0.001$) and the difficult setting ($P < 0.001$). For the easy setting, 11 of 32 participants (34%) graded laryngoscopy more difficult with the covered laryngoscope compared with the standard laryngoscope. This was statistically significant ($P = 0.001$). For the disposable laryngoscope, 7 of 32 participants (22%) considered laryngoscopy more difficult than with the standard laryngoscope. Again, this was statistically significant ($P = 0.008$).

For the difficult simulator setting, 22 of 32 participants (69%) found laryngoscopy more difficult with the covered laryngoscope, and 22 out of 32 participants (69%) found laryngoscopy more difficult with the disposable laryngoscope when compared with the standard laryngoscope. This was statistically significant ($P < 0.001$ for both comparisons). Again, there was no difference between the covered and disposable laryngoscopes ($P = 0.87$).

Profile of participating anaesthetists

Participating anaesthetists had variable experience, with a median of 2.75 years (11 months to 25 years). There were no significant correlations between experience and laryngoscopic grading for any combinations of simulator and laryngoscope (Table 2).

Discussion

There was a variation in the laryngoscopy grade obtained by the participating anaesthetists for every laryngoscope-simulator combination. Grade 1 visible, epiglottis, vocal cords; grade 2 visible, epiglottis, posterior glottis only; grade 3 visible, epiglottis only; grade 4, none of glottis or epiglottis. Grades 1 and 2 are considered easy to intubate, and grades 3 and 4 are difficult to intubate [17]. Standard: stainless steel, Macintosh type, size 3 laryngoscope. Covered: standard laryngoscope covered with size 3 plastic blade cover (LaryGard™, Penlon). Disposable: disposable, plastic, Macintosh type, laryngoscope blade, size 3 (Crystal™, Penlon).

![Figure 2](https://academic.oup.com/intqhc/article-abstract/18/1/17/1803680)  
*Figure 2* The percentages of anaesthetists grading laryngoscopy at the four grade levels for each simulator difficulty setting/laryngoscope combination. Grade 1 visible, epiglottis, vocal cords; grade 2 visible, epiglottis, posterior glottis only; grade 3 visible, epiglottis only; grade 4, none of glottis or epiglottis. Grades 1 and 2 are considered easy to intubate, and grades 3 and 4 are difficult to intubate [17]. Standard: stainless steel, Macintosh type, size 3 laryngoscope. Covered: standard laryngoscope covered with size 3 plastic blade cover (LaryGard™, Penlon). Disposable: disposable, plastic, Macintosh type, laryngoscope blade, size 3 (Crystal™, Penlon).
Table 2 Correlation between anaesthetist experience and laryngoscopic grading, calculated by Spearman’s correlation by ranks

<table>
<thead>
<tr>
<th>Simulator setting</th>
<th>Standard MAC3</th>
<th>Covered MAC3</th>
<th>Disposable MAC3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy</td>
<td>( P = 0.34, )</td>
<td>( P = 0.29, )</td>
<td>Incalculable(^1)</td>
</tr>
<tr>
<td></td>
<td>( r = 0.02, )</td>
<td>( r = 0.19, )</td>
<td></td>
</tr>
<tr>
<td>Difficult</td>
<td>( P = 0.4, )</td>
<td>( P = 0.72, )</td>
<td>( r = -0.11 )</td>
</tr>
<tr>
<td></td>
<td>( r = -0.17 )</td>
<td>( r = 0.24, )</td>
<td></td>
</tr>
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</table>

\(^1\)Every anaesthetist graded laryngoscopy with a standard MAC3 blade and easy simulator setting, as grade 1. Therefore, correlation was impossible to perform.

The worsening of laryngoscopic grade in already difficult cases was expected to have more of a clinical impact. For instance, it has been estimated that less than 1% of grade one laryngoscopies, around 20% of grade two laryngoscopies, 80% of grade three laryngoscopies, and 100% of grade four laryngoscopies are associated with difficulty in intubating the trachea [16]. Therefore, it can be imagined that for an easy intubation, if using disposable equipment changed the laryngoscopy grade from one to two, this might cause only a small increase in the difficult intubation rate. However for more difficult cases, changing of a grade two laryngoscopy to grade three, or grade three to grade four, would have a much greater impact on the difficult intubation risk.

Reasons for increased difficulty

Successful tracheal intubation depends on adequate visualization of the larynx, adequate illumination of the larynx, and operator skill. The physical characteristics of laryngoscopes dictate the visualization and illumination obtained at direct laryngoscopy. It is clear that the physical characteristics of standard reusable stainless steel laryngoscope blades, standard blades when used with a blade cover, and disposable (plastic) laryngoscope blades are different. Therefore, it is entirely possible that the view of the larynx obtained at laryngoscopy could be changed. It has previously been shown that the use of laryngoscope blade covers reduces the illumination provided for direct laryngoscopy by around two-thirds [18]. We found that laryngoscopy grade was worsened with both disposable blades and blade covers. This raises the possibility that the actual view of the larynx obtained with the disposable equipment is inferior, and this is not just an effect of lower illumination. We suspect that the anecdotal reports of increased difficulty performing tracheal intubation reflect the use of unfamiliar equipment, with a combination of different visualization and illumination of the larynx. It is possible, however, that if the anaesthetists were more familiar with the equipment they used that the differences in laryngoscopic view might have been less. Nevertheless, currently the use of single-use equipment in the UK is largely limited to tonsillectomy surgery. Hence, most anaesthetists will be similarly unfamiliar with this equipment.

Strengths and limitations

There is debate as to whether high-fidelity patient simulation is an adequately validated tool for assessment of anaesthetists [19,20]. Although it has been advocated for assessing equipment [19], such a role for simulators is in its infancy. In theory, a high-fidelity patient simulator allows standardized, reproducible intubating conditions with which to compare technique between operators or equipment performance within operators. In general terms, anaesthetic simulation has been shown to provide good overall realism as assessed by a group of anaesthetists with various levels of experience [21]. In support of the validity of the simulation, changing from the easy to difficult setting on the anaesthetic simulator increased the laryngoscopic grade for a significant proportion of our participants using standard Macintosh laryngoscopes. A similarly designed study found a comparable worsening in laryngoscopic grading with different disposable blades [15]. We are aware of any studies quantifying specifically how similar laryngoscopy of simulation mannequins is to real patients. However, modern high-fidelity simulators seem to provide a reasonable model of tracheal intubation, and we can see no reason why the comparative performance of laryngoscopes should be different in a clinical study.

We admit that ideally the study should have been blinded as well as randomized. However, by the nature of the use of laryngoscopes, it was impossible to blind the participants to the laryngoscope used. The best we could do was to blind the participants to the difficulty of the simulator setting. Although not perfect, they did not know whether to expect difficulty or not. In addition, it would seem better to standardize whether participant could use laryngeal or cricoid pressure. However, this is how the scale is used in clinical practice. Admittedly, had we not found a positive result, recording an increased need for laryngeal or cricoid pressure may have increased the sensitivity of the scoring system used.

It could be argued that we should have performed a similar study on real patients. We believe it would be unethical to subject anaesthetized patients to repeated laryngoscopies with different laryngoscopes. We accept that a prospective randomized trial to comparing the incidence of difficult intubation...
with each laryngoscope would be the gold standard for answering the question we have posed. However, given that difficult direct laryngoscopy has an incidence of around 3% [22], if we were to assume that a 50% increase in this rate was significant, we calculated this would require a study size of 1300 patients to detect such a difference. Given there may be a difference in the performance between the available makes of single-use equipment [15], several options for single-use laryngoscopy would have to be studied, increasing the necessary sample size further. It could take months and probably years to plan and perform such a study. Using the simulator has allowed us to perform multiple intraobserver comparisons with standardized conditions. The use of real patients would add the additional variable of changing patient anatomy. By being able to simulate difficult intubation conditions, this further increased the power of the study. We feel the potentially fatal consequences of any adverse airway events caused by changing laryngoscopy practice demands a much more rapid answer. Using the simulator has allowed us to identify a potential clinical problem more quickly.

Risk management of changing practice

The recommendation to change equipment for laryngoscopy was because of the fear of transmission of CJD. The risk of transmission from reusable sterilized surgical instruments and medical equipment is currently unquantifiable [3]. In contrast, the possible anaesthetic and surgical morbidity is becoming apparent [5–9]. We have shown that the use of disposable equipment changes the view obtained at direct laryngoscopy and that this effect is greater for simulated difficult intubation. The potential morbidity and mortality resulting from an increased rate of difficult laryngoscopy is a very real risk-management issue.

For the proposed change in laryngoscopy practice, it would seem prudent to replicate the methods of the American Anesthesia Patient Safety Foundation regarding policy issues [19]. This is based on the principle of establishing a burden of proof regarding practices or policies that seem to deviate from existing norms. In short, if a change in practice from the existing norm is proposed, it can only be adopted if clear and convincing data are presented showing that an alternative policy is equally safe. In this study, we have sought and failed to find such evidence. Our study adds to the increasing body of evidence [15,18] that single-use laryngoscope equipment may be inferior to reusable stainless steel laryngoscopes. It is unclear whether single-use blades are inherently inferior to the standard Macintosh reusable blades or if anaesthetists require training and experience to improve their expertise with this equipment. Therefore, we would urge that current advice to use disposable equipment for anaesthesia for tonsillectomy be reconsidered, until these matters are resolved.

It is possible that improved manufacturing and design may overcome this problem. However, this would generate even more single-use equipment, which would also need to be assessed. High-fidelity patient simulation appears to be an appropriate tool for assessing and comparing new equipment. More importantly, the performance of anaesthetists using the equipment could be assessed in a controlled environment that is risk free to the patient.

Acknowledgements

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