

RESPIRATION AND THE AIRWAY

Assessment of competency during orotracheal intubation in medical simulation

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Abstract

Background: Clinicians performing orotracheal intubation need to be competent to perform this technical skill safely. It is recognized that aggressive force applied during direct laryngoscopy may damage the oropharyngeal soft tissue; however, force is seldom considered in assessment of competency. The objective of this study was to explore the force applied during orotracheal intubation as a method of further discriminating between levels of competence. We sought evidence of construct validity in the form of discriminant, criterion, and concurrent validity. We hypothesized that the force generated during simulated intubation could serve to discriminate skill level among clinicians.

Methods: A convenience sample of 35 health-care professionals filled a self-reported questionnaire and were then divided into the following three groups: Group 1, experts ($n=16$); Group 2, intermediates ($n=7$); and Group 3, novices ($n=12$). They then intubated a part-task trainer (Laerdal Airway Management Trainer) after reviewing a procedural video and engaging in one practice session. Intubations were recorded. Outcome measures were as follows: (i) force applied to the epiglottis, calculated (in newtons) using two superimposed pressure-sensitive films (Prescale; Fujifilm, Madison, WI, USA) on the laryngoscope blade; (ii) number of attempts required to achieve successful intubation; (iii) time to intubation; and (iv) hand position.

Results: Of the four outcome measures, only force applied during orotracheal intubation was able to discriminate between groups. All data are reported as the mean (sd). There was a significant difference in force between groups during orotracheal intubation [one-way ANOVA; experts, 102 (25) N; intermediates, 134 (28) N; and novices, 153 (43) N], with a significant difference ($P<0.05$) noted between novice and experts on *post hoc* analysis.

Conclusions: Force exerted during intubation provides meaningful information when attempting to discriminate intubation skill level. Force demonstrated criterion validity and could be used as a measure of competency during training.

Key words: airway; anaesthetic techniques, laryngoscopy; education; equipment, laryngoscope

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Editor's key points

- Pressure-sensitive films placed on the tip of a laryngoscope blade can be used to measure the force applied on a laryngoscope blade during tracheal intubation.
- The force exerted during intubation might serve as an objective and valid measure to discriminate skill level among a group of health-care professionals.

Competency-based education is dependent on assessment to monitor and support trainee progress. In the simulated and clinical environment, checklists are often used to determine whether a practitioner is competent and safe with a technique, such as intubation.¹ A measure is said to have criterion and construct validity if it can readily differentiate the expert from the intermediate and the novice. Measures such as success at intubation, time to intubation, and hand position on the laryngoscope are often included in checklists, but it is not clear if they are valid assessment tools.

It is recognized that aggressive force during successful intubation may cause oropharyngeal trauma and may lead to complications, such as lacerations, sore throat, laryngospasm, and perforation. Although using appropriate force during oro-tracheal intubation is a patient safety imperative, it is rarely measured and not used to determine competency.

The force applied during tracheal intubation can be measured using sensors, transducers, and special pressure-sensitive films secured to the laryngoscope. The force exerted varies depending on the type of blade,²⁻⁵ patient characteristics,^{2,6} and the experience of the operator,^{5,7,8} with a tendency for experts to use less force than non-experts. We therefore hypothesized that the force exerted during intubation might serve as an objective and valid measure to discriminate skill level among a group of health-care professionals.

Methods**Volunteers and groups of experience**

Over a 2 day period, health-care professionals who participated in a team training workshop at a local Simulation Centre were asked to participate in the present study. A self-report questionnaire (two dichotomous and two contingency questions) exploring profile and skill with oro-tracheal intubation was administered to participants. Based on these results, we categorized participants based on experience level with intubation, which we categorized as expert, intermediate, or novice. *A priori*, we labelled as 'experts' those who had performed more than 30 intubations on humans per year and had more than 3 years of experience with intubation. We labelled as novices those who had performed fewer than five intubations on humans or had less than 3 months of experience with tracheal intubation. Finally, we labelled as intermediates those excluded from expert and novice groups. All questionnaires were coded and reviewed only after the participants completed the study. One author (A.C.), who categorized the skill level of the participants, was blinded to the study scores. Finally, we asked if the participants had previous experience with intubation manikins, and all had had at least one previous practice session during the course of their training. Nonetheless, all volunteers were allowed to view a procedural training video and had at least one practice session on the Laerdal Airway Management Trainer manikin before data collection.

Experimental set-up

Our outcomes measure included the following: (i) time to intubation; (ii) intubation success; (iii) hand position; and (iv) force applied during intubation. After the practice session, participants were asked to intubate the manikin using direct laryngoscopy. They were allowed to move the bed up or down according to preference and to hyperextend the neck. 'Time to intubation' was recorded by noting the time the blade of the laryngoscope was inserted into the mouth for intubation and stopped once the tool was removed. All data are reported as the mean (SD). Intubation success was also captured by noting first lung inflation and by direct observation of the tube through the cords. Hand position was evaluated by video recording the placement of the hand on the laryngoscope from the right side at a 90° angle to the participant. Hand placement was determined as being primarily on one of three areas of the laryngoscope: the handle, the junction of the handle and the blade, or the blade. Time to intubation and success of intubation were determined by two individuals (A.C. and J.G.). Hand placement was determined by one individual (A.C.); when in doubt, a team of three individuals adjudicated (A.C., J.G., and K.L.).

Force measurement

The force applied by the participant during tracheal intubation was first calculated by measuring pressure with two superimposed pressure-sensitive films (Prescale; Fujifilm, Madison, WI, USA) fixed with adhesive tape on the under surface of a Macintosh no. 4 laryngoscope, as previously described.² Force (in newtons) was then calculated using the formula, where pressure is measured by the film and the pressurized area of the film calculated by software (see below). All data are reported as the mean (SD).

As opposed to electronic sensors, these films do not change the shape or the weight of the laryngoscope such that the movement and technique of the participant are not altered. More importantly, these films are commercially available and relatively easy to set up. The pressure-sensitive films had the same area (15 mm² × 40 mm²), and care was taken to have the film surpass the tip of the blade by 2 mm so that pressure exerted on the very tip of the blade could be recorded at the blade tip.

In a pilot project,^{9,10} we had limited our experimentation with one range by using only an ultra-super low-pressure film (known as LLLW). The film saturated at 0.6 MPa, and higher force magnitude could not be measured. In this study, therefore, we applied (by superimposing one over the other) two films with different sensitivity ranges; the ultra-super low-pressure (LLLW, 0.2–0.6 MPa) and the super low-pressure film (LLW, 0.5–2.5 MPa). This allowed us to increase the range of pressure and force measured during the intubation. In this manner, the pressure from 0.2 to 2.5 MPa could be measured and recorded. Each sensor consists of two layers secured together: a micro-encapsulated red colour-forming layer (A) and a colour-developing layer (C). The colour-developing layer shows red tint densities that were then analysed by a pressure distribution mapping system (FPD-8010E; Fujifilm), and forces were calculated by measuring the surface areas via the software. The forces determined from each sensor were averaged. To cut the film to the desired dimensions and to avoid broken microcapsules in manipulating (A), a laser (Samourai UV Laser Marking System; DPSS Laser Inc., Santa Clara, CA, USA) was used. The final assembly is shown in Figure 1.

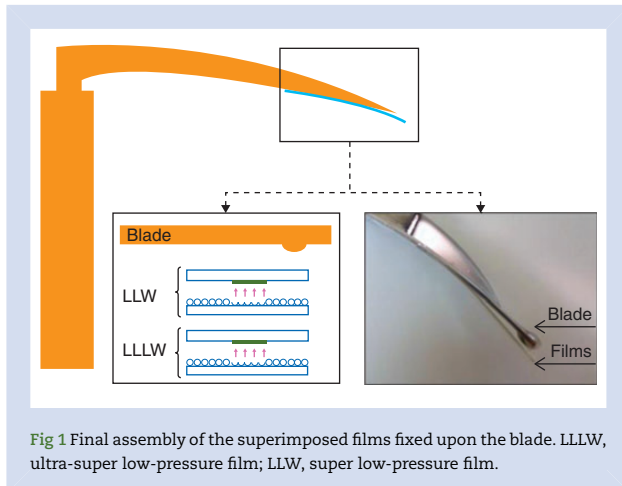


Fig 1 Final assembly of the superimposed films fixed upon the blade. LLLW, ultra-super low-pressure film; LLW, super low-pressure film.

Sample size and statistical analysis

In a previous pilot study,⁹ we measured the force during intubation using the LLLW film to be 94 (65) N among a group of experts. Assuming that novices would use higher forces than experts during intubation, as an estimate of effect we calculated a sample size in each group to be 10 using an α value of 0.05 and β value of 0.80. A convenience sample is considered. Mean differences among groups were calculated using a one-way ANOVA with a *P*-value of <0.05 considered significant. Where appropriate, a *post hoc* analysis between groups was performed using the Tukey–Kramer method for groups with unequal *n*.

Results

Groups and categorization

Thirty-five participants enrolled in the study, and based on the results of the self-reported intubation questionnaire described above and classification defined *a priori*, 16 participants were categorized as experts, seven as intermediates, and 12 as novices.

Intubation success and time to intubation

All intubations were successful on the first attempt and placement through the vocal cords confirmed by first lung inflation and direct observation after the intubation.

Overall, the average time needed to intubate the manikin was 19 (9) s. The time required for intubation did not vary significantly among groups (Fig. 2): 17 (5) s for the experts, 19 (3) s for the intermediates, and 21 (14) s for the novices ($P=0.51$). One may note that apart from two novice participants with very long intubation times, all times are fairly close.

Hand position

Overall, the favoured technique was to grasp the laryngoscope at the junction of the handle and the blade, followed by the handle, and finally the blade (Fig. 3). No differences were noted between groups as to the technique used during intubation, and the majority of participants in all groups used the junction (50% of the experts, 57% of the intermediates, and 50% of the novices). The blade was held by 31% of the experts, 43% of the intermediates, and 33% of the novices and the laryngoscope handle by 19% of the experts, 0% of the intermediates, and 17% of the novices.

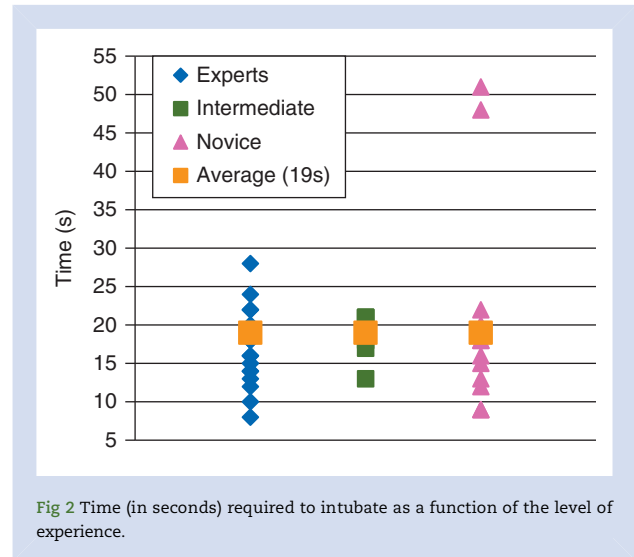


Fig 2 Time (in seconds) required to intubate as a function of the level of experience.

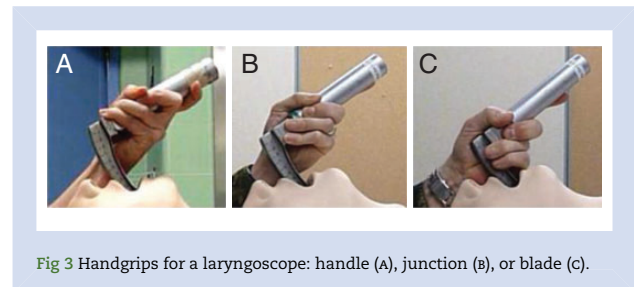


Fig 3 Handgrips for a laryngoscope: handle (A), junction (B), or blade (C).

Force applied to the epiglottis

With respect to the force applied to the epiglottis during tracheal intubation, the average for the whole cohort was 130 (10) N. The maximal force exerted was 227 N and the minimal force 53 N. Despite this variation, there were significant differences between groups, with experts exerting 102 (25) N, intermediates 134 (28) N, and novices 153 (43) N ($P=0.0009$; Table 1 and Fig. 4).

A *post hoc* analysis of the groups was performed using the Tukey–Kramer method. The large confidence intervals showed the important variation in the force used among the participants; a significant difference was noted between the novices and experts (Table 2).

We measured the correlation coefficient of time to intubation and force applied during intubation to determine whether participants using more time also applied more force. We found that $r^2=0.245$ (non-significant). There was no correlation between the time to intubate and the force applied.

For comparison purposes, we defined an acceptable critical force limit for intubation as being equal to the average force used by experts plus one standard deviation. To be deemed competent with intubation, a participant would need to exert no more than 129 N during intubation. At this critical force limit, 94% of experts met this expectation, 43% of intermediates, and 42% of novices.

Discussion

A simple methodology has been developed to measure the force applied on a laryngoscope blade during orotracheal intubation on

a manikin. This technique is able to discriminate skill level among clinicians performing orotracheal intubation and could be used to assess competency in the technique of intubation.

Two pressure-sensitive films of different sensitivities (Prescale; Fujifilm) were placed on the tip of a laryngoscope blade, and the pressure generated during intubation was subsequently

calculated by the software (FPD-8010E; Fujifilm). The force used during intubation was then calculated from the intensity of discolouration of the film and the area of the film discoloured. This discolouration and intensity were measured using laser software. Out of four criteria tested (success at intubation, time, laryngoscope handling, and force), only force applied to the epiglottis was able to discriminate among a group of practitioners. The ability to measure force using this fairly simple technique may allow a more sensitive means of measuring individual competency during training. We did note that 6% of experts, 57% of intermediates, and 58% of novices used a force during intubation above what we set as an acceptable standard. We did not compare our cut-off value with the performance of the participants as measured by a robust checklist or poor rating scale to see whether there was a correlation. This could be work for future study. However, the idea that one measure could provide valid, reliable, and discriminatory information regarding the skill level of an individual is appealing and novel.

Other groups have also been interested in measuring force during intubation. Carassiti and colleagues² chose the same pressure-sensitive film, LLLW (Prescale; Fujifilm), for their research, but the forces measured were lower than ours [average forces exerted by the anaesthetists, 39 (22) N, and by the trainees, 45 (24) N]. The reasons could be that the level of experience was not clearly defined, they used a different manikin (SimMan® Laerdal Airway Management Trainer), the force on tip of the laryngoscope was not measured, and they used only one pressure-sensitive film instead of two. The film they used (LLLW) is limited to pressure varying from 0.2 to 0.6 MPa, thus higher pressures are neglected. In fact, we found in a pilot project using the LLLW film^{9,10} several situations where the pressure could not be measured because of complete saturation at 0.6 MPa. In that situation, the films showed the same red tint for every pressure higher than the maximum considered, and the software (FPD-8010E; Fujifilm) could not differentiate pressures above 0.6 MPa. To capture a larger range of high and low pressure, we used two films superimposed on one another as previously described by Čada and colleagues.¹¹ Given that the sensitivity of the films used in our study and those by Carassiti and colleagues² are not the same, we cannot directly compare results, although they did note similar trends of higher forces used during intubation by less experienced individuals.

Given that our research was performed in simulation-based contexts, future research will need to be conducted using *in vivo* methods to determine whether our results, and the results of earlier studies, remain stable in those contexts. Carassiti and colleagues¹² have already analysed the force and the pressure *in vivo* in order to compare two types of laryngoscopes. We have begun the process of doing so, but given that few tests on humans have been performed yet, we have identified some challenges. For instance, the blade and films need to be protected by a transparent, impermeable, elastic elastomer that can be inserted into a patient's mouth. Condoms without lubricant may meet this

Table 1 Force (in newtons) according to level of experience

	Expert (n=16)	Intermediate (n=7)	Novice (n=12)
	113.5	158.5	212.5
	127.5	138.5	141
	142	86	111
	123	116	118.5
	103.5	128	125
	111	171	106
	94.5	141	118
	110.5		139
	107		182
	111.5		207
	60.5		227
	80.5		150.5
	88		
	74.5		
	124.5		
	52.5		
Average force (N)	102 (25 sd)	134 (28 sd)	153 (43 sd)

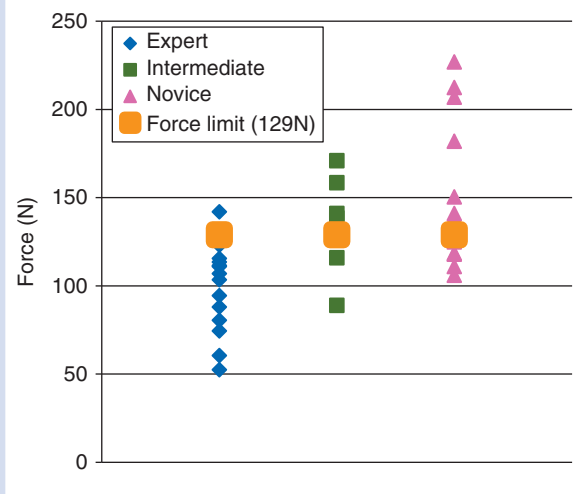


Fig 4 Force (in newtons) in terms of level of experience.

Table 2 Tukey–Kramer method

Group comparison	Difference in mean force (N)	95% Confidence interval	Significant (P<0.05)	Critical range
Expert vs intermediate	-33	-69 to 4	No	3
Expert vs novice	-52	-82 to -21	Yes	6
Intermediate vs novice	-19	-57 to 19	No	2

requirement of needing to preserve the films. The transparency of the material enables a sufficient light level for a proper intubation. Nevertheless, an additional layer of latex between the films and the trachea could lead to difficulties in comparing forces applied.

Those experiments *in vivo* might lead to different force means from those measured on a manikin. The significant difference between the groups should be analysed statistically, and we may change our criterion to discriminate intubation skill level. We think that the intubations performed *in vivo* would decrease the overall amount of force for a healthy patient, because the manikin simulated harder tissue than that *in vivo*. Indeed, it is generally accepted by experts that manikins do not perfectly simulate the mechanical properties of human tissue. We could also extend our research to several pathologies that affect the trachea. This being said, we do feel that force measured during intubation on a manikin may be a surrogate for determining proficiency with orotracheal intubation before performing on a real patient.

The three other criteria measured in our study (success of intubation, time to intubation, and handling of the laryngoscope) did not differentiate skill level. All participants were successful on the first attempt, the average time to perform the intubation was not significantly different, and there was no correlation between the time to intubate and the force applied. In previous research, a noticeable difference had been observed in terms of time to intubation, but this was found only between experts and novices.¹³ This earlier research did not define the start and stop points when measuring the time to intubation. This suggests that common approaches to determine 'competence' in intubation may not be as sensitive to ranges in performance as we demonstrated here or that at the very least, an additional metric could be incorporated into formative and summative assessments.

We observed and recorded three techniques with respect to handling the laryngoscope; the blade, the junction, or the handle. We noted no differences among groups as to their preference, and the majority of participants favoured the use of the junction. We did not measure the precise angle of the blade with respect to the plane of the chest of the manikin, but Delson and colleagues¹⁴ installed on a laryngoscope a three-dimensional force and torque sensor and a three-dimensional magnetic position sensor, which allowed them to measure angles and position. During human intubations, it was observed that experts were inclining the head more in comparison with the novices, and the laryngoscope was held in a more horizontal axis with respect to the floor.

We believe that the results of our study have implications regarding the assessment of competency during orotracheal intubation. Traditional metrics of performance for intubation, such as success of intubation, time to intubation, and the position of the hand on the laryngoscope, failed in this study to discriminate skill level among clinicians. According to our findings, these traditional measures are poor predictors of competency and need to be used with caution during trainee assessments. Simply put, the ability to intubate a manikin successfully within a specific time frame may not be sufficient evidence of the competency of a trainee to perform orotracheal intubation. These traditional metrics are not sensitive indicators of competency.

In contrast, force during intubation did discriminate between clinicians and demonstrated construct validity in distinguishing novice from expert performance. The ability to measure force can significantly improve our assessments of trainees; force appears to be a more sensitive indicator of competency than the other outcome measures we evaluated. As a measure, force may be

an important component of the process of intubation, which could be included as part of a training programme. The addition of pressure sensors may be a way of improving the ability to distinguish between performers in summative assessments and may help to provide feedback during formative assessments.

An important aspect of our findings is that the measure of force can be replicated easily and can be incorporated into training programs without too much cost. The films are commercially available, and the set-up of the films on the blade is straightforward. The pressure measurement of the films can be done using a reference chart, but the use of software improves accuracy.

Our study has limitations. The acceptable force generated during intubation would need to be validated using a larger cohort for purposes of standard setting. In our study, we arbitrarily set our standard to be equal to or less than one SD above the average force used by experts. We would not expect learners to achieve expert-level performance during training, so we did apply the principle that the goal of training is to achieve competency and not expertise; hence, the allowance to be one SD above the mean expert force. Again, one would need further study to generate consensus around standard setting, but the idea is that there is a point at which force may be excessive.

Although we did look at intubation technique, we only viewed the position of the hand on the laryngoscope, but we know that there may be important yet subtle differences in the angles used during intubation and the positioning of the head that we did not study in our research.

No doubt, the manikin itself may be playing an important role in the force required during intubation, and one would also need to correlate the force generated during human intubations. One may argue that the force required to intubate a manikin is higher than in a real patient, and as such, our results do not apply to the human situation. We believe that these differences in force between manikin and human intubation would be relative, and we would simply need to develop criteria for the human setting.

Finally, a much larger cohort would be needed to validate the use of force as an objective measure of skill and competence.

In conclusion, among a cohort of professionals with varying levels of experience, the force applied to the blade during intubation may serve as a suitable measure of discriminating among different skill levels of clinicians. Force demonstrated criterion and concurrent validity and could be used as a tool to assess competency during orotracheal intubation for both formative and summative purposes.

Authors' contributions

Study design: K.L., J.G., A.C., N.N.

Data collection: A.C.

Data analysis: K.L., J.G., W.T., N.N.

Manuscript: K.L., J.G.

Manuscript review: W.T.

Medical and simulation expert: K.L.

Engineering expert: N.N.

Statistics: W.T.

Declaration of interest

None declared.

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