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Simulation-based Randomized Paired Cross-over Comparison of Direct versus Video-assisted Laryngoscopy for Endotracheal Intubation by Inexperienced Operators

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Abstract

Purpose: Direct laryngoscopy (DL) is the standard technique for endotracheal intubation. Video-assisted laryngoscopy (VL) has emerged as an alternative, particularly for difficult airway management. Nevertheless, DL and VL have not been systematically compared for simulation-based endotracheal intubation by inexperienced operators.
Method: A prospective, randomized cross-over study was carried out at Lund University Faculty of Medicine, Malmö, Sweden, in 50 medical undergraduate students with no previous experience of endotracheal intubation in manikins or patients. Identical manikins (Rescue Anne™, Laerdal AS, Stavanger, Norway) were consecutively intubated using DL with the Macintosh-type blade, and VL with the hyper-curved Glidescope™ blade. Similarly designed and extensive instructional films on DL and VL techniques were shown to each study participant immediately before each training session, comprising ten consecutive individual intubation attempts with that specific device. No further instructions or feedback were provided by the study investigators.
Results: The VL technique was found to be overall faster than DL, and also associated with fewer intubation failures ($P = 0.0209$), dental manipulations ($P < 0.001$), and oesophageal intubations ($P < 0.0001$).
Discussion: Since VL for endotracheal intubation by inexperienced operators was more successful and associated with fewer adverse events than was DL, we propose that VL might be preferable to DL for endotracheal intubation by less experienced users. Further research is however strongly encouraged to validate these findings.

Keywords: Intubation, endotracheal; Laryngoscopy, direct; Laryngoscopy, video-assisted; Training; Video

1. Introduction

Regular training and practice is required to achieve and maintain adequate competence of endotracheal intubation.[1,2]

Direct laryngoscopy (DL) has been the gold standard procedure for endotracheal intubation since the mid-twentieth century.[3] Nevertheless, DL may be

Abbreviations: DL, direct laryngoscopy; VL, video-assisted laryngoscopy

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difficult to learn, regular clinical practice is required to maintain skills acquired, and failure of intubation, dental trauma or oesophageal intubation may result.[1,2,4,5]

Video laryngoscopy (VL) is an established clinical alternative, particularly for difficult airway management.[6,7] In devices for VL, a camera at the edge of a Macintosh-type or hyper-angular laryngoscope blade provides high-resolution online view of the laryngeal orifice, calling for less manipulation of the neck or (with the hyper-angular blade) tongue. Hyper-angular-type VL devices have been reported to provide better view of the larynx, and also more successful endotracheal intubation, than DL.[8–10]

This simulation-based randomized cross-over study was designed for structured comparison [11] of VL and DL for simulation-based endotracheal intubation by inexperienced operators. Primary outcome measures were the numbers of, and time required for, successful intubation within five minutes, and the numbers of dental manipulation, and oesophageal intubation.

2. Subjects and methods

2.1. Study setting

This prospective, randomized paired cross-over study, designed to evaluate learning curves (success rate, time required) and complication rates (dental manipulation, oesophageal intubation,) of DL and VL for endotracheal intubation by inexperienced operators, was approved by the regional Human Ethics Review Board, Lund, Sweden (Dnr 2012/173), and carried out according to institutional guidelines of good clinical practice at the Clinical Research Center, Lund University, and Skåne University Hospital, Malmö, Sweden.

2.2. Study subjects

Fifty 4th- to 7th-term undergraduate students at Lund University Faculty of Medicine, previously inexperienced in endotracheal intubation, were recruited using a web-based online time-booking system.

Before study inclusion, statistical software producing random numbers had been used to assign each inclusion number (1–50) a binary code (similarly distributed between the inclusion numbers) indicating the cross-over design order of the study interventions (i.e. DL followed by VL, or vice versa). The study participants were given inclusion numbers in the order in which they were being consecutively included.

Oral and written information about the purpose and design of the study was provided, and individual written consents were obtained, on inclusion. Before being included, each study participant formally denied any previous experience of endotracheal intubation (in manikins or patients) based on DL, VL or any other technique.

2.3. Study design

Each participant was observed by a study investigator (EG or ND) during the DL and VL sessions of intervention, each comprising ten consecutive intubation attempts, in identical airway management trainer manikins (Rescue Anne™, Laerdal AS, Stavanger, Norway), positioned onto standard hospital beds in two identical adjacent rooms at the research site. The participants started with DL (followed by VL), or with VL (followed by DL), according to their individual randomization codes (Fig. 1).

2.4. Instructional films

Standardized basic information on the DL and VL techniques was initially provided by brief (approximately five-minute) similarly designed and directed instructional films in Swedish language, comprising relevant aspects on airway anatomy together with technical descriptions shown in four sequences repeated at different camera shooting angles.

Beta versions of the instructional films were directed and produced in collaboration between the two investigators and the project leader, and then scrutinized by ten senior anaesthesiologists. Their individual comments, obtained independently, were used to finalize the films.

Each study participant was initially asked to carefully watch each film, and no further oral instruction, advice or comment was provided during the following study intervention.

2.5. Study interventions

Adult standard-size (inner diameter 7.0 mm) endotracheal tubes, prepared with stylets, were used. Tubes and manikin airways were appropriately and regularly lubricated according to recommendations by the manikin manufacturer.

Macintosh size-3 blades were used in all DL, and hyper-angular adult standard blades in all VL (Glidescope™, Verathon Medical, Bothell, WA, USA), study interventions.

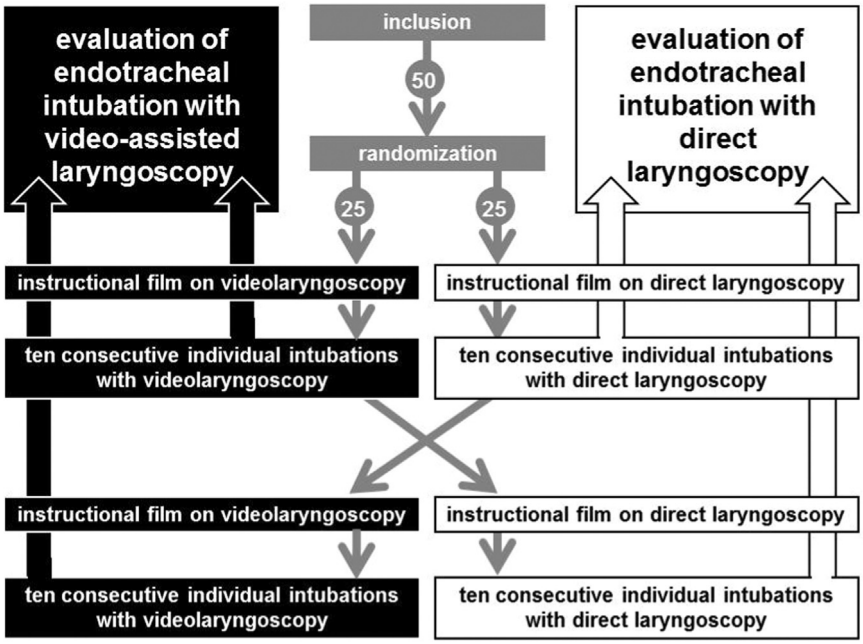

Fig. 1. Schematic view of the randomized cross-over study design. Fifty Swedish medical undergraduate students with no previous experience of endotracheal intubation (in manikins or patients) were randomized to carry out either ten consecutive endotracheal intubations with video-assisted laryngoscopy followed by ten intubations with direct laryngoscopy, or vice versa, after having been shown brief instructional films on either laryngoscopic technique before each study session. The two study techniques were analyzed by paired non-parametric statistical comparisons.

2.6. Outcome measures

Time and scores (according to defined criteria) were consecutively recorded in the study protocol by the study investigator throughout each session of ten consecutive intubations with DL or VL without interrupting, or commenting on, any action by the study participant.

The time required for successful intubation was measured from oral insertion of the laryngoscope blade until verified appropriate inflation of air, failed intubation as no verified endotracheal positioning of the tube within a pre-determined maximum five-minute period, dental manipulation as production of tooth click sounds in the manikin, and oesophageal intubation as a failed attempt at ventilation. Each attempt at intubation was allowed to continue for a msximum period of 300 seconds, regardless of adverse events (dental manipulation, oesophageal intubation). The intubation success rate was calculated as the number of successful intubations divided by the total number of successful and failed attempts at intubation with that technique.

2.7. Rating of instructional films

Soon after each DL or VL session of intervention had been completed, the study participant was asked to estimate, by global rating, on a ten-level (0–10) visual analogue scale (VAS), to what extent that particular instructional film was considered to have promoted individual practice and learning of endotracheal intubation, and also the perceived level of overall difficulty with that technique.

2.8. Statistical analysis

Before the study was designed, 38 subjects had been calculated to be required to confirm – with 80% statistical power, and 95% statistical probability, based on paired comparisons – a difference in time for successful intubation of at least 10 $\pm$ 15 seconds between the DL and VL techniques.

Non-parametric data is reported as median with interquartile range (IQR) in paranthesis.

The Wilcoxon signed rank sum test was used to compare time required for successful intubation, and score ratings, and the Fischer´s exact test to compare proportions of dental manipulation, and of failed or oesophageal intubation, between the DL and VL study interventions.

All information obtained was recorded in Microsoft Excel^{TM} spread sheets (Microsoft Corp., Redmond, Washington, USA) and analysed with the Statistical Package for the Social Sciences (SPSS), version 22.0,

statistical software (IBM Corp., Armonk, New York, USA).

The level of statistical significance was set at $P < 0.05$.

3. Results

3.1. Study subjects

Fifty study participants were included, and all of them completed the DL and VL sessions of intervention.

3.2. Time required

Significantly shorter time was required for the first ($P < 0.0001$) and ninth ($P = 0.008$) successful intubations with VL than with DL (Fig. 2).

3.3. Success rate

Intubation with VL was also found to be associated with significantly higher success rates within 60, 120, 180, 240, and 300 s (Fig. 3).

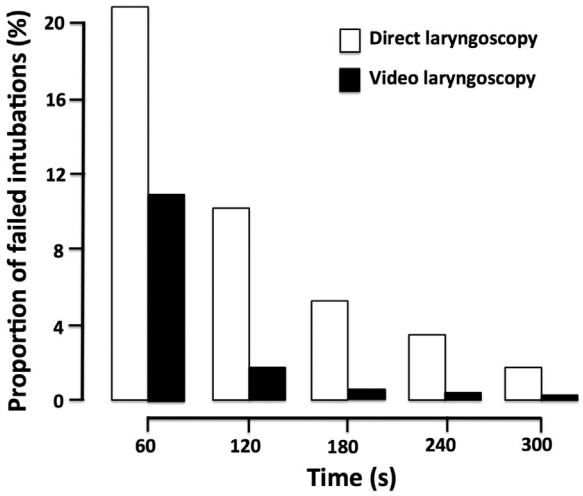

Fig. 3. Inability over time of positioning an endotracheal tube into the trachea with direct or video-assisted laryngoscopy by inexperienced operators. Ten individual intubation attempts in identical upper airway manikins were made with either technique by 50 Swedish undergraduate medical students, evaluated prospectively with a randomized cross-over study design, after having been shown brief instructional films on either laryngoscopic technique before each study session. The Fisher's exact test was used to compare the study techniques with respect to their rates of intubation failure over time.

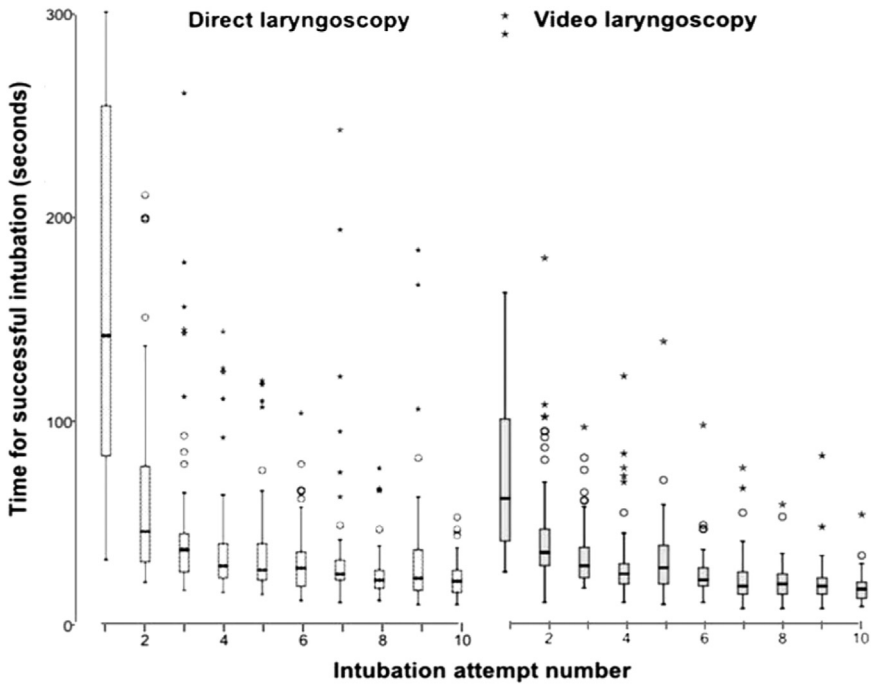

Fig. 2. Learning curves for endotracheal intubation with direct or video-assisted laryngoscopy by inexperienced operators. Ten individual intubation attempts in identical upper airway manikins were made with either technique by 50 Swedish undergraduate medical students and evaluated prospectively with a randomized cross-over study design after having been shown brief instructional films on either laryngoscopic technique before each study session. Horizontal lines indicate medians, boxes 1st to 3rd quartile ranges, and vertical lines ranges (not including outliers, marked by circles and asterixes).

Table 1
Proportions of adverse events associated with 20 individual endotracheal intubation attempts, made according to defined standard instructions with direct and video-assisted laryngoscopic techniques in identical airway manikins by 50 Swedish undergraduate medical students with no previous experience of endotracheal intubation (in manikins or patients), evaluated with a randomized cross-over study design. Failure of endotracheal intubation was defined as inability of positioning the tube into the trachea within five minutes. Fisher's exact test was used to compare adverse event rates between the study interventions.

	Adverse event rates (%) associated with endotracheal intubation based on		Level of statistical significance (*P* value)
	Direct laryngoscopy (500 procedures)	Video-assisted laryngoscopy (500 procedures)	
Failure of endotracheal intubation within 5 min	1.8	0.2	0.021
Dental manipulation	8.0	3.0	< 0.001
Oesophageal intubation	15.8	1.0	< 0.0001

3.4. Adverse events

In addition, VL was associated with more successful intubations and fewer complications (Table 1). The rate of failed intubation was lower ($P = 0.021$) with VL than with DL, and so were the rates of traumatic dental manipulation ($P < 0.001$), and oesophageal intubation ($P < 0.0001$).

3.5. Rating of instructional films

Individual globally rated levels of film quality were similar for DL and VL (median 8 (IQR 8–9) vs. 8 (8–9) VAS units; $P > 0.300$), whereas the DL technique was rated as more difficult to apply than the VL technique (overall difficulty 5 (4–6) vs. 3 (3–4) VAS units; $P < 0.0001$).

4. Discussion

4.1. General remarks

Main findings of this study, primarily designed to compare simulation-based practice by inexperienced operators of the two techniques currently most frequently used for clinical endotracheal intubation by enabling repeated attempts under highly standardized conditions[11] – that endotracheal intubation based on VL is faster, more successful and less traumatic than with DL in the hands of operators with no previous experience of either technique – are partly new and may imply potential advantages of VL for less frequently performed intubation procedures by new operators. Enabling safer endotracheal intubation by less experienced operators in prehospital or emergency room settings[1,2,5] might prevent vital organ dysfunction, severe short- and long-term morbidity, and even fatal outcome.

4.2. Time required

By also providing on-screen imaging, considerably facilitating individual bedside teaching, video-assistance seems to be particularly valuable during early intubation training. Although this opportunity was never used during the study sessions, the less than half as long time required for successful intubation on the first attempt with VL, together with its lower total number of failures, suggest (as also perceived by most study participants) that simulation-based endotracheal intubation with VL is easier to comprehend and manage than with DL.

Use of DL by emergency or paediatric physicians has been reported in unpaired evaluations to enable more rapid endotracheal intubation in manikins.[12,13] compared with the use of VL. Those findings are not necessarily incompatible with ours, considering that we evaluated inexperienced operators only, and that the difference in time for successful intubation between the study interventions gradually decreased with the number of consecutive individual attempts. This tendency towards reduced differences between the DL and VL techniques over time might reflect that basic technical skills are similarly easily acquired with either technique. However, considering that no single intubation took more than 100 s from the sixth attempt onwards with VL – in contrast to several late attempts with DL – it still seems that intubation with DL is more difficult to learn and practice. Accordingly, acquiring appropriate intubation skills with DL by paramedics has been reported to call for regular intubation practice.[2] Whether basic intubation skills with VL acquired by

new operators, as in the present study, are also better maintained over time, compared with those acquired with DL, remains to be studied.

4.3. Success of intubation

In agreement with studies of emergency intubation[12,13] or based on simulation,[14] but in contrast to other simulation-based studies,[15,16] we found a higher success rate of intubation with VL than with DL. Plausible explanations for the lack of difference in success rate between the techniques in the latter studies[15,16] might be some previous experience of endotracheal intubation among the operators, and less standardized study design.

4.4. Adverse events

Lower rates of oesophageal intubation have recently been reported in emergency intubations with VL than with DL by operators with limited experience.[12,13] The lower incidences of dental trauma and oesophageal intubation with VL accordingly found here suggest that VL for endotracheal intubation by inexperienced operators might be both safer and less harmful than DL. Consequently, VL – not requiring a direct optical view of the larynx – is recommended for difficult airway management including failure with DL.[6,7,17,18]

4.5. Study design

Although DL and VL have also been compared by others for endotracheal intubation,[9,10,14,19,20] this is the first simulation-based study with a prospective randomized cross-over design, enabling intra-individual paired comparisons based on repeated individual intubation procedures. Other advantages of the present study are the high number of participants, reproducible and identical methods of teaching (by consistently designed instructional films), manikins providing identical anatomical upper-airway conditions, and well-defined, easily assessable outcome measures.[11]

To our knowledge, instructional films have not been used in previous studies to provide systematic and similar basic information on techniques to be compared for upper-airway management. We do not consider our main findings to reflect differences in quality of information, teaching or preparation between the study interventions, since the films were similar in design and duration, and also similarly (and highly) rated for quality by the study participants.

This study was not designed to compare the two interventions with respect to the quality of laryngeal view or the local force applied over time (impulse, i. e. duration and extent of local pressure), since VL has been shown by others to provide better view of the larynx, and also (if managed appropriately) to exert less local pressure on hypopharyngeal soft tissue, than DL.[8,19]

4.6. Manikins versus humans

On condition that enough lubricant is being applied (as in the present study), standard airway manikins used for endotracheal intubation training might by considered to provide identical conditions for repeated intubation attempts by different study participants over time. The clinical relevance of results obtained in manikins might however still be challenged. Although we cannot be certain that manikin airways are similarly favourable for application of the VL or DL techniques, the ability of VL to solve airway problems associated with the use of DL [6,7] might be interpreted to reflect actual differences between DL and VL in humans similar to those confirmed by us in manikins.

Although manikins provide defined airway conditions,[11] they normally do not allow detection or evaluation of soft-tissue damage from manual handling. Damage to soft tissue, mainly in the oropharynx, has been reported to result from clinical use of hyper-angulated laryngoscope blades for VL,[21] presumably managed much like Macintosh-type blades by operators with previous experience mainly of DL. Therefore, it remains unknown whether individual techniques used for intubation with VL in our manikins would have been associated with more soft tissue damage in real patients or not. Although VL was shown to be both easier and safer to use than DL for endotracheal intubation in manikins by inexperienced operators, it seems that specific and appropriate teaching and training of VL based on hyper-angulated blades in this respect might be particularly important in operators previously familiar with DL only.[21]

4.7. Conclusions

Since VL for endotracheal intubation was easier to learn and safer to use by inexperienced operators, we suggest that VL might be preferred to DL for endotracheal intubation by less experienced users. Although it remains to be evaluated whether intubation skills with VL are also better maintained over time by inexperienced operators, we propose VL for endotra-

cheal intubation to be used more by operators with less frequent intubation practice in prehospital and emergency room settings. Further research is however strongly encouraged to validate these findings.

Short statement of key findings

This simulation-based randomized cross-over study shows that video-assisted laryngoscopy for endotracheal intubation by inexperienced operators is more successful and associated with fewer adverse events than is direct laryngoscopy. These results suggest that video laryngoscopy might be preferred to direct laryngoscopy for endotracheal intubation by less experienced operators, but further research is required to confirm these findings.

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Authorship attribution

This study was planned and designed by all authors and ethically applied for by EG, ND and JÅ.

Drafts of the two instructional films were directed and recorded by EG and ND in close collaboration with JÅ, and all authors contributed to the final versions.

The study subjects were recruited and included by EG and ND, and the study techniques were compared and evaluated in manikins by EG and ND.

The results obtained were compiled by EG and ND, and analyzed by EG, ND and JÅ.

The first draft of the manuscript was prepared by EG and ND, and all authors contributed to the final version.

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Other disclosures

The authors declare no conflicts of interest.

Ethical approval

The study design was approved by the regional Human Ethics Review Board, Lund, Sweden (Dnr 2012/173).

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