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MANIKIN AND SIMULATION STUDY

Personal protection equipment for biological hazards: Does it affect tracheal intubation performance?☆

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Personal protection equipment

Summary

Purpose: Personal protection equipment (PPE) is recommended for use during airway management of patients with highly contagious respiratory tract illness. While its use in chemical hazards and its effect on airway management has been assessed previously, there has been no research assessing whether this equipment affects the ability to perform tracheal intubation. It is the intention of this investigation to answer this question.

Methods: Eighteen workers at various level of training were asked to wear three different types of PPE while performing four different types of tracheal intubation. The PPE used included the eye shield, face shield and the "Dustmaster™". The intubation techniques were direct laryngoscopy, intubation through the intubating laryngeal mask (Fastrach™) and flexible bronchoscopy using the eyepiece and an eyepiece with camera attached. We assessed the time to intubate as well as the incidence of oesophageal intubation. A short questionnaire was used to examine participants' subjective experiences of wearing the various types of PPE.

Results: There was no significant effect on the time to intubation for any of the methods studied. However, all subjects found that the face shield was uncomfortably hot to wear. Fiberoptic bronchoscopic intubation using the eyepiece was particularly difficult with all of the PPE used due to the distance of the subjects' eye from the eyepiece.

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Conclusion: Although the use of PPE may not affect the length of time to intubate manikins, certain types of PPE may be uncomfortable to wear and noisy. Further research is needed to investigate whether this could be a problem in the clinical setting or in actual difficult intubations.

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Introduction

Nosocomial transmission of severe acute respiratory syndrome-associated coronavirus (SARS-CoV) to health care workers (HCW) has been a notorious characteristic of this disease. During the 2003 outbreak, about 20–50% of all SARS-CoV cases in Hong Kong, Singapore and Canada occurred in HCW.^{1,2} Such viruses are a constant threat and recent reports of ‘avian flu’ (in particular H5N1 virus) are now another cause for concern.

Pulmonary complications are a prominent feature of these diseases and patients frequently require intensive respiratory therapy and mechanical ventilation. Unfortunately airway management such as bag and mask ventilation, intubation, suctioning and mask based oxygen and drug delivery appear to have been important vectors of disease transmission.³ Wearing a correctly fitted face mask (either surgical or particulate respirator type N95) while caring for SARS-CoV patients appears to be protective.^{1–5} A variety of personal protection equipment (PPE) has also been suggested for use by HCW in all aspects of patient treatment during such outbreaks.⁶ The level of PPE chosen for high-risk procedures such as tracheal intubation is extremely important for both the patient and the treating physician. Rigid prerequisites for the protective ability of such equipment are obviously essential but it is also important that the protective clothing does not impede HCW during clinical procedures, particularly crucial events such as airway management.

Previous studies have investigated the use of protective clothing for chemical hazards^{7–13} and their impact on airway management. Though PPE for chemical and biological hazards may share some common characteristics (e.g. eye and face shields) chemical hazard PPE is often composed of different materials ranging from disposable Tyvek® to polyvinylchloride ‘splash suits’.^{8–10} In contrast, water-resistant or water-proof gowns were the most frequently used clothing during the SARS-CoV outbreak in 2003.^{14–21}

During outbreaks of these diseases, anaesthetists are frequently involved in patient airway management, resuscitation and intensive care. This is not because these patients are particularly difficult to intubate, but because the World Health

Organization (WHO) guidelines⁶ stipulate that the most experienced operator should secure the airway in order to minimise delay and secretion dissemination. At such times, tracheal intubation is often necessary and, although other airway devices such as the laryngeal mask may facilitate some temporary ventilation and oxygenation, a properly sealed tracheal tube is often mandatory in the care of these patients.

At this stage the optimal level of protection for the HCW performing such high-risk procedures has yet to be found, and in the past the Centre of Disease Control and Prevention (CDC)²² have suggested a number of combinations of PPE. The PPE recommended during the 2003 SARS-CoV outbreak included eye and facial protection,^{14–19} and powered air purifying respirators (PAPR).^{14,15,17–21} Recently the WHO has proposed its recommendations for avian flu⁶ which includes goggles or eye shields for eye protection. We have, therefore, taken these recommendations as well as reviewed the most commonly used PPE employed during the SARS outbreak in China, Hong Kong and Canada and have adopted this as our ‘control PPE’. This control group has then been compared with two other types of PPE to investigate if they had an impact on the ability or time taken to perform tracheal intubation and the comfort of the individual.

The objective of this study was to examine the impact of three types of PPE on the ability of anaesthetists and anaesthesia trainees to intubate manikins using four different intubation techniques.

Methods

Approval for the study was granted by the local institutional review board. Four consultant anaesthetists and 14 anaesthetic trainees participated in this prospective comparative study after giving informed consent. All subjects were staff members of the same large teaching hospital and were selected based on their availability to participate in the study. The presence of learning curves for practical skills in anaesthesia is well recognised and a 90% success rate after 57 attempts has been suggested in a study of anaesthesiologists.²³ Using a

mono-exponential model, Smith et al.'s learning curve indicated that after 45 intubations (five half-lives) the trainee anaesthesiologist draws close to their 'expert' fiberoptic intubation time.²⁴ All participants in this study had at least this level of experience. Subjects who had previous experience wearing PPE prior to the commencement of this study or those who had previous opportunities to intubate patients while wearing PPE were excluded from the study. Three weeks before the study, all subjects underwent qualitative fit testing of the N95 face mask. This was performed well before the study to parallel the clinical situation during outbreaks when there is often insufficient time for testing prior to tracheal intubation.

For anaesthetists the length of time since obtaining the fellowship was recorded, and for anaesthetic trainees, their level of training was noted. The subjects practised on the manikin using all the airway devices for 30 min immediately prior to their participation in the study to familiarise themselves with the equipment. This aimed to eliminate "learning phenomena" during the study because the times for the various procedures might change as a result of familiarity with the equipment.

Since the use of PPE during tracheal intubation of patients with infectious respiratory illness is mandatory, the control group wore the basic level of PPE for use in this situation.² We had the eye shield group as our control and compared this with the two other types of PPE as described. Subjects applied the PPE in the order control PPE, PPE 1 and then PPE 2 (see Table 1). An observer with wide

experience in the use of infection control measures and in particular PPE, performed a final inspection after the PPE was applied to ensure that the subjects were dressed in compliance with the above recommendations (Plate 1).

Tracheal intubation methods

Tracheal intubation of a Laerdal Airway Management Trainer (Laerdal Medical Corp., Oakleigh, Vic., Australia) was performed using the following methods.

Direct laryngoscopy

A standard Macintosh size 3 blade was used for direct laryngoscopy. The time measured was from the moment the anaesthetist grasped the laryngoscope until the tracheal tube was placed in the trachea, the cuff inflated and ventilation via the tracheal tube was successful.

Intubating laryngeal mask airway (iLMA)

A size 4 iLMA was used for intubation along with the corresponding 7.5 mm internal diameter (I.D.) cuffed tracheal tube. After the device was placed correctly in the manikin's airway, the cuff of the laryngeal mask airway was inflated with 20 ml of air. Ventilation through the iLMA was tested with a self-inflating bag. The first split time was taken from picking up the iLMA to the first inflation of the manikin's lungs. The bag was then disconnected and the tracheal tube was inserted. The second split time was recorded as the cumulative time to ventilation via the tracheal tube. The third split time was

Table 1 Types of PPE used

	Control PPE	PPE 1	PPE 2
Theatre cap	✓	✓	✓
N95 mask	✓	✓	✓
Non-sterile latex gloves	✓	✓	✓
Water-resistant surgical gown secured around the neck and surrounding the lower torso, the cuffs of which were secured under the gloves	✓	✓	✓
Other	Eye shield (lenses and frames: Timeley Medical, Carlsbad, USA)	Transparent face shield (Delta Medical Pty. Ltd., Brisbane, Australia)	Dustmaster™ Air Filter Unit with the Medimaster Headtop (also known as "Air-Mate"—3M Pty. Ltd., USA). The hood was placed on the head of the subject and the battery pack and electric pump secured around the subjects' waist

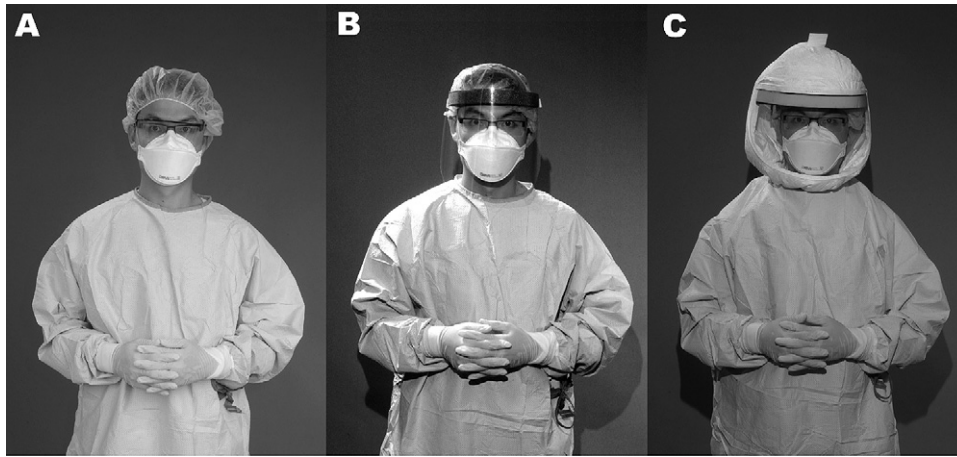


Plate 1 Comparison of PPE. (A) Control PPE (eye shield); (B) PPE 1 (transparent face shield); (C) PPE 2 (Dustmaster™ Air Filter Unit with the Medimaster Headtop).

recorded following removal of the laryngeal mask and successful ventilation via the tracheal tube.

Fibreoptic intubation using the bronchoscopic eyepiece

A lubricated size 9 cm Berman Intubating Airway (Vital Signs, Totowa, NJ, USA) was inserted into the mouth of the manikin to assist oral fibreoptic intubation and to parallel the clinical situation of using fibreoptic bronchoscopic intubation in anaesthetised patients. An intubating fibreoptic bronchoscope (Olympus LF-GP, Olympus America Inc., USA) was used for all cases and the tracheal tube was passed over the bronchoscope and into the trachea of the manikin. The first split time recorded was from picking up and inserting the Berman airway until the carina was first visible through the bronchoscope. The second split time was cumulative and recorded as successful ventilation via the tracheal tube.

Fibreoptic intubation with an attached camera/video screen

A lubricated size 9 cm Berman Intubating Airway was inserted into the mouth of the manikin. A fibreoptic bronchoscope with an attached camera (Olympus OTV-S4, Olympus America Inc., USA) mounted on the eyepiece and video screen attached to the eyepiece was used to visualise the manikin's airway on a video screen during the intubation. Split times were taken in a similar method to fibreoptic intubation using the eyepiece alone.

A 7.5 mm I.D. Portex Profile Soft-Seal Cuff (Portex™ SIMS Portex Ltd., Hythe, Kent, UK) was used for all tracheal intubations except for the size 4 intubating laryngeal mask airway where a 7.5 mm I.D. Fastrach™ tracheal tube (Fastrach™,

LMA North America, San Diego, CA) was used. All tubes and mask airways were lubricated with water-soluble lubricant.

Successful intubation was confirmed by observation from the bottom of the manikin of the inflated tracheal tube cuff in the trachea in addition to successful inflation of the lungs. Failure was defined by the occurrence of oesophageal intubation. Any instance of endobronchial intubation was also recorded.

At the completion of the study, subjects were given the following questions to answer:

- Q1. Which PPE provided the best conditions for all methods of tracheal intubation?
- Q2. Which PPE provided the worst conditions for all methods of tracheal intubation?
- Q3. Do you have any general comments about any of the PPE used?

Statistical methods

All the intubation times were analysed by repeated measures of analysis of variance (ANOVA). When the normality assumption on the residuals was violated, log transformation was applied to the intubation times before performing repeated measures ANOVA. Since this is a prospective observational study examining the impact of various types of PPE on tracheal intubation techniques, power calculations were based partly on previous work focussing on the impact of chemical protective equipment on tracheal intubation.^{7–13} However, patients with infectious respiratory illnesses requiring tracheal intubation will have significant degrees of respiratory failure and are often intolerant to prolonged intubation attempts. Based on a pilot study we aimed to detect not less than a 5 s difference

Table 2 Intubation times in seconds ($n = 18$)

	Control PPE	PPE 1	PPE 2	<i>p</i>
Direct laryngoscopy	24.2 ± 6.5	21.7 ± 4.2	22.2 ± 6.6	0.15
iLMA time 1	14.7 ± 3.0	14.4 ± 3.5	14.0 ± 3.5	0.61
iLMA time 2	36.3 ± 7.1	33.2 ± 5.0	34.2 ± 8.4	0.22
iLMA time 3	72.0 ± 16.0	66.8 ± 8.8	64.4 ± 11.6	0.24
FO eyepiece time 1	28.3 ± 10.6	42.8 ± 35.4	36.1 ± 21.6	0.43
FO eyepiece time 2	61.9 ± 23.8	70.2 ± 32.3	63.8 ± 21.7	0.68
FO TV time 1	24.3 ± 8.5	24.4 ± 10.9	21.4 ± 3.9	0.84
FO TV time 2	54.9 ± 10.9	52.1 ± 15.9	48.8 ± 11.5	0.30

Values in mean ± S.D. iLMA = intubating laryngeal mask airway. iLMA times: (1) iLMA time 1 = grasping iLMA to first inflation of the manikin's lungs via iLMA; (2) iLMA time 2 = grasping iLMA to first inflation of the manikin's lungs via tracheal tube (with iLMA in place); (3) iLMA time 3 = grasping iLMA to final inflation of the manikin's lungs via tracheal tube and after removal of iLMA. FO eyepiece = fiberoptic bronchoscopic intubation using bronchoscopic eyepiece. FO TV = fiberoptic bronchoscopic intubation using an attached camera/video screen. FO times (FO eyepiece and FO TV): (1) Time 1 = initial handling of Berman airway to when carina was first visible; (2) Time 2 = initial handling of Berman airway to first inflation of manikin's lungs via tracheal tube.

between the times for direct laryngoscopy and intubation with an estimated standard deviation of 7 s. The required sample size was 17 participants with an 80% power of the test at the 0.05 level of significance.

Results

Experience of the consultant anaesthetists ranged from 1 year post fellowship to 20 years. The level of training of the trainees ranged from first year to final year in the Australian and New Zealand College of Anaesthetists training system.

Table 2 shows that none of the three types of PPE had a significant effect on the ability to perform tracheal intubation in the manikin with

the different intubation techniques. The intubating laryngeal mask airway and fiberoptic intubation using the eyepiece both provided the longest intubation times. These times are significantly longer than direct laryngoscopy and fiberoptic intubation using the video screen.

There were no oesophageal intubations; however, there were four endobronchial intubations. One was associated with direct laryngoscopy while wearing the control PPE. The other three cases occurred with control PPE, PPE 1 and PPE 2, respectively, using the intubating laryngeal mask. The study size was insufficient to show any statistical difference in the incidence of endobronchial intubation.

Table 3 shows the results to the questionnaire at the completion of the study. Sixty-seven percent

Table 3 Results for questionnaire

	Control PPE	PPE 1	PPE 2	Undecided
Q1. Which PPE provided the best conditions for all methods of tracheal intubation?	0% ($n = 0$)	0% ($n = 0$)	67% ($n = 12$)	33% ($n = 6$)
Q2. Which PPE provided the worst conditions for all methods of tracheal intubation?	0% ($n = 0$)	67% ($n = 12$)	5% ($n = 1$)	28% ($n = 5$)
Q3. Do you have any general comments about any of the PPE used?	Hot and sweaty ($n = 1$)	Fogging up ($n = 12$), claustrophobic ($n = 2$) High internal reflection making it difficult to look around ($n = 2$) Difficult with (prescription) glasses on, made view look distant and blurry ($n = 1$)	Difficult with fiberoptic eyepiece due to distance from protective shield to eye ($n = 8$) Difficult to communicate ($n = 2$) Visual fields restricted ($n = 1$)	

of subjects recorded that PPE 2 generally provided the most comfort for all types of intubation, while the same percentage of subjects rated PPE 1 as having the worst. Numerous comments from the subjects highlighted the uncomfortable environment that PPE 1 produced, with most subjects sweating while wearing the water-resistant surgical gown and face shield despite the air-conditioned environment (23°C and 55% relative humidity) in which the study took place. The face shield in PPE 1 often became fogged especially during longer intubation techniques. Subjects frequently needed to adjust their head into different positions to maintain visibility. The positive pressure produced by the Dustmaster™ device in PPE 2 appeared to protect against fogging.

Other issues apart from the level of comfort using PPE included the following:

1. All PPE devices produced problems when using the bronchoscopic eyepiece. The distance between the eyes of the subject and the bronchoscopic eyepiece meant that the participants needed to move their head across the eyepiece to view the entire image.
2. One subject found that the combination of bifocal eyeglasses, PPE 1 and the bronchoscopic eyepiece produced difficult conditions for intubation. Frequent adjustment of the visual axis was necessary to obtain the optimal image.
3. Another subject wearing glasses for myopia found PPE 1 and the bronchoscopic eyepiece difficult for intubation, finding the visual image poorly focused.
4. Reflections from the back of the face shield proved to be troublesome with PPE 1 by two subjects.
5. Two subjects noted that the noise from the battery-powered pump in the Dustmaster™ in PPE 2 made it difficult to hear instructions from personnel directing them to the various intubation stations.

Discussion

This study examined the impact of selected PPE on the ability to perform tracheal intubation using a standard airway manikin. The use of a manikin does not equate to an actual intensive care patient and their environment. However, this study does allow an important practical comparison of three types of PPE while undertaking a variety of different intubation techniques. If PPE impedes the ability to perform tracheal intubation, then its use during high-risk procedures on patients with infec-

tious respiratory disease could be impractical and possibly dangerous. Furthermore, its role as an infection control barrier could also be compromised if problems during tracheal intubation necessitated adjustment of the PPE thereby increasing the infection risk of the user.

We have included a wide range of tracheal intubation experience in the selected participants as would mirror the actual clinical situation during respiratory illness outbreaks closely where both qualified anaesthetists as well as anaesthetic trainees would be required to perform this task.

Suggestions have been made that a minimal amount of PPE (consisting of surgical mask/N95, surgical gown and gloves) can provide adequate protection for HCW² and that more complicated protection may increase the risk of contamination during the de-gowning process (Dr. WH Seto; Department of Microbiology, Queen Mary Hospital, Hong Kong, personal communication). We have examined several types of PPE so that a more informed decision may be made when choosing the appropriate type of PPE for tracheal intubation.

After each type of PPE was applied, the subjects performed the different methods of tracheal intubation randomly in four separate rooms to avoid subjects assisting each other during the study. Times were compared to define the optimal method for intubation. Cumulative split times were taken for the iLMA to differentiate possible variations in times during the intubation that may be associated with the type of PPE worn. Similarly during the two bronchoscopic methods, the time until the carina was first visualised was distinguished from the time to pass the tracheal tube over the bronchoscope and ventilate the lungs to highlight possible effects by the PPE.

We found that the type of PPE does not influence the time taken to intubate a manikin with any particular method. We did not perform a comparison with no PPE (i.e. no mask, gloves, surgical gown or eye protection) because HCWs are required to wear some level of PPE while intubating patients with infectious respiratory diseases and, in fact, it is prudent to do so even in asymptomatic patients.

The fact that the PPE did not prove to affect the intubation times may be related to the fact that the tracheal intubations were carried out on manikins and that difficult airway management conditions were not examined. Certainly further research examining various intubating conditions should be performed to the detail the effects of this equipment.

All the subjects felt that PPE 1 made them uncomfortably hot, that fogging of the face shield

frequently occurred and that they would prefer to avoid this particular type of PPE. The proposal that patients with highly infectious respiratory illness should be placed in negative pressure isolation rooms, which frequently produces a drop in the number of air changes,¹⁷ may compound this temperature problem. Reflections from the back of the face shield in PPE 1 were a problem for two subjects and may be detrimental during tracheal intubation, especially if fogging occurs as well. The use of prescription glasses by subjects wearing PPE 1 while performing fiberoptic intubation with the eyepiece also appears to be troublesome. Two subjects found this combination made the procedure very difficult but not impossible. We suggest that if contact lenses are available, then these should be worn prior to applying the PPE.

In contrast, the control PPE and PPE 2 produced favourable conditions for tracheal intubation, particularly PPE 2. All subjects felt that the air powered respirator of PPE 2 countered the insulating and subsequent heating effect from the water-resistant surgical gown. However, the DustmasterTM produced a low-level background noise that made hearing difficult. Although assistants were able to overcome this by raising their voices, the possibility that this may contribute to difficulties in communication during the intubation and subsequent management of a patient with a respiratory illness should be considered.

Direct laryngoscopy was the fastest method of tracheal intubation followed by fiberoptic intubation with camera/video screen with fiberoptic intubation using the eyepiece and iLMA together as the slowest (see Table 2). Frequently direct laryngoscopy may require closer proximity of the subject to the manikin's airway than the other intubation techniques. This is of concern when performing tracheal intubation on patients with diseases spread by droplet or contact transmission.

It should be noted that the laryngeal mask airway intubation method used in this study provided three occasions where the manikin was ventilated during the procedure. This initial ventilation (mean values for PPE groups: 14.0–14.7 s) was in fact faster than the time for ventilation following direct laryngoscopy (mean values for PPE groups: 21.7–24.2 s). Although there is concern that ventilation other than through a tracheal tube may lead to dissemination of secretions, we felt that initial ventilation via the laryngeal mask would be of lesser risk than for face mask ventilation. On the other hand the average time with no ventilation using the bronchoscopic eyepiece method ranged from 61.9 to 70.2 s for all types of PPE. This may impact on the main-

tenance of oxygenation in patients with respiratory illness when the fiberoptic bronchoscope using the eyepiece is used.

The use of the eyepiece of a fiberoptic bronchoscope is difficult when any protective eyewear is worn. This occurred with all three types of PPE but the distance from the subjects' eye and the protective shield and, therefore, bronchoscopic eyepiece was greatest for PPE 2 and least for the control PPE. This resulted in all subjects expressing concern if this type of technique was to be used while wearing PPE. We suggest the use of a video screen, if available, with fiberoptic intubation as this avoids the problems that eye protection creates and allows the physician to avoid placing their hands in close proximity to their face.

The occurrence of three endobronchial intubations is a concern, although the study was not designed to indicate if this is a higher risk while wearing PPE. The possibility that PPE may potentiate endobronchial intubation should be investigated further. In particular, PPE 2 may interfere with the detection of endobronchial intubation as the use of a stethoscope to check for the presence of bilateral chest sounds is impossible due to the head being covered and with the background noise level.

This study has several limitations. The principle limitation was the use of a manikin. Apart from the anatomical differences between manikins and patients, there is the failure of manikins to respond physiologically to tracheal intubation. The study took place in controlled conditions without the extra stress created by performing life-saving procedures on patients with respiratory failure. In addition the possibility of the participants contracting the respiratory illness during the procedure could not be simulated. All intubations were of the same grading and further work needs to be performed focusing on more difficult airway management.

In summary we have assessed different types of PPE and their influence on four common intubation techniques. We found that, although none of the types of PPE had a measurable effect on intubation times, the practical problems of excessive heating and fogging while wearing a transparent face shield device may be problematic during tracheal intubation of patients with respiratory distress. There were also difficulties in viewing the fiberoptic bronchoscopic eyepiece through the face shields of PPE 1 and PPE 2. The study showed that using bronchoscopic methods was inferior to iLMA, which allowed significantly earlier ventilation of the lungs. This suggests that the iLMA should be used in preference to the fiberoptic bronchoscope when difficulties in

viewing the larynx are experienced during direct laryngoscopy.

Background noise produced from the Dust-master™ was undesirable but the device was otherwise comfortable. In this laboratory environment we were not able to study or properly simulate situations such as unexpectedly difficult intubation, but we believe this could be a concern in such circumstances.

Implication statement

The use of personal protection equipment during tracheal intubation of patients with infectious respiratory illnesses is essential for the safety of health care workers. While its use in chemical hazards and its effect on airway management has been examined previously its effect on intubation techniques in the setting of a biological hazard has not been assessed before and this study will appraise this aspect critically.

Conflict of interest statement

There are no competing interests amongst the authors relating to publication of this manuscript.

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