

Emergency airway management in a simulation of highly contagious isolated patients: Both isolation strategy and device type matter

Running title: Airway management in isolated patients

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1 **ABSTRACT**

2
3 **Objective:** To compare six airway management devices in three isolation scenarios
4 (portable isolation unit (PIU), personal protective equipment (PPE), standard
5 protection measures) regarding their effect on airway management.

6 **Methods:** Thirty anesthesiologists working in emergency medical services performed
7 airway management on mannequins in three isolation settings, using six different
8 airway management devices in randomized order: Standard Macintosh laryngoscope,
9 Airtraq™SP-video-laryngoscope, i-gel™, LMA-Fastrach™, Ambu fiberoptic-aScope™
10 and Melker cricothyrotomy-set. They were assessed regarding time-to-ventilate
11 (primary outcome) and rating of difficulty handling the device.

12 **Results:** In 86% (standard protection) and 85% (PPE) of attempts, airway
13 management was achieved in <60 seconds, irrespective of the device used; in the
14 PIU setting, only 69% of attempts succeeded within this timeframe ($p<0.05$).

15 Median time-to-ventilate was shorter for standard protection (23 seconds) and PPE
16 (25 seconds) compared to the PIU (38 seconds, $p<0.001$). In the PIU setting, the
17 fiberscope took the longest (median 170 seconds), while i-gel was the quickest
18 (median 13 seconds). The rating of difficulty (visual analogue scale VAS 0-100) was
19 significantly different between the isolation scenarios: Airway management was most
20 difficult with PIU (VAS=76), followed by PPE (35), and standard protection (9,
21 $p<0.01$).

22 **Conclusion:** Wearing personal protective equipment produced similar times-to-
23 ventilate as standard protection in anesthesiologists, but was subjectively rated more
24 difficult. The portable isolation unit permitted acceptable times-to-ventilate when
25 excluding fiberscope and cricothyrotomy.

1 Supraglottic airway devices proved to allow the fastest airway management in all
2 isolation scenarios, thus being highly recommendable if a portable isolation unit is
3 used and emergency airway management becomes necessary.

4

1 INTRODUCTION

2
3 The 2014 Ebola outbreak was extremely challenging for healthcare workers
4 (HCW) worldwide. Treating patients was demanding and limiting disease
5 transmission proved to be difficult. Between January 2014 and March 2015, 815
6 healthcare workers in Sierra Leone, Liberia, and Guinea became infected with
7 Ebola.¹ Between August and December 2015, 27 Ebola patients were treated in the
8 United States and Europe. Of these 27 patients, 24 were evacuated from Africa and
9 22 were HCW. Three HCW became infected with Ebola without having been to Africa
10 by caring for these 24 evacuated Ebola patients. Therefore, the ratio between
11 patients managed outside Africa and infected HCW was only 8:1.² Such a high
12 infection risk underlines the importance of adequate patient isolation.

13 Not only Ebola, but also other highly contagious diseases such as Avian
14 Influenza, Middle East respiratory syndrome (MERS), severe acute respiratory
15 syndrome (SARS) or pulmonary tuberculosis may require a near-perfect patient
16 isolation in order to protect HCW.

17 Different approaches to prevent transmission are used when dealing with
18 patients with highly contagious infections. One is to wear extensive personal
19 protective equipment (PPE), usually consisting of protective suits, head covers, and
20 respirator systems with air filtration. This equipment however, is cumbersome and
21 may negatively affect medical performance.³⁻⁶

22 Alternatively - and especially recommended for air medical transportation -
23 airtight containment units such as a portable isolation unit (PIU) may be used to
24 isolate patients.^{7,8} In 2015, the Swiss Air Medical Rescue Services (Rega) evacuated
25 a British HCW from Sierra Leone to London using such a PIU after she became
26 infected with Ebola following a protocol breach doffing her PPE.⁹

1 The negative influence of PPE on the performance of medical personnel is
2 known, but no data is available on the effect of PIUs on carrying out emergency
3 medical procedures.

4 In order to care for isolated patients, the execution of medical procedures,
5 especially time-sensitive tasks like airway management, must be possible with as
6 little disruption as possible. Emergency airway management procedures are
7 standardized and success is readily defined as the ability to ventilate the lungs. Such
8 scenarios can be realistically simulated in mannequins. We therefore used airway
9 management as a surrogate outcome parameter to determine the influence of PIUs,
10 PPE, and standard protection measures on medical procedures.

11 Specifically, the purpose of this randomized controlled mannequin study was
12 to find out how long each individual airway management procedure would take (i.e.,
13 the primary outcome). In addition, we wanted to gain insight on subjective ratings of
14 difficulties experienced when performing medical emergency tasks in such settings.

MATERIALS AND METHODS

Study Design and Setting

To evaluate the impact of patient isolation on airway management, we invited 30 anesthesiologists working in the local ground or helicopter-based emergency medical services (EMS) to participate in this randomized controlled mannequin trial, conducted at Bern University Hospital, Bern Switzerland.

The study was reviewed by the Cantonal Ethics Committee (KEK) Bern (KEK-number: Req_2016_00106, 18.03.2016). After signing informed consent, participants performed airway management on mannequins, using six different procedures in three different settings representing different techniques of patient isolation.

The order of the six airway management procedures as well as the order of the isolation setting was randomized. All participants were familiar with the six airway management techniques before the study onset. The three different settings were:

1) A standard setting in which exam gloves (cosaLine Nitril Comfort, Cosanum, Oxford, UK) were used,

2) A setting in which participants wore personal protective equipment (PPE). According to hospital standards, we used level C personal protective equipment consisting of: two pairs of gloves (Biogel® Indicator® Underglove, Mölnlycke Health Care, Schlieren, Switzerland; Sempermed® supreme surgical gloves sterile, Vienna, Austria), chemical protective clothing (Tychem C™ with socks, DuPont™ Wilmington, USA), a hard hat (Versaflo™S-605-10, 3M™, Minnesota, USA), and a respirator and a Powered Air Purifying Respirator (PAPR) (Jupiter™ Powered Air Turbo Unit, 3M™, Minnesota, USA) (Figure 1).

3) A setting in which the mannequin was isolated in a PIU, (VenIONPIU® portable isolation unit, TB-Safety Ltd., Frick, Switzerland;) used by Rega, the Swiss Air

1 Medical Rescue (Figures 2 & 3).^{9,10} The VenIONPIU® is a temporary, single-use
2 isolation chamber that prevents cross-contamination from patient to HCW. Built-in
3 one-size gloves on both sides and at the head of the chamber enable HCW to
4 access the chamber.

5 Airway management was performed on three identical Laerdal® Airway
6 Management Trainers (Laerdal® Airway Management Trainer, Laerdal, Stavanger,
7 Norway). Participants ventilated mannequins using a facemask before commencing
8 with the airway management technique corresponding to the randomized order.
9 Successful airway management was defined as visible thorax excursion. We
10 stressed the importance of measuring time-to-ventilation. One attempt per device in
11 each setting was allowed and an attempt was defined as unsuccessful when
12 participants decided to abort the procedure, when esophageal intubation occurred, or
13 when an attempt took longer than 240 seconds. All airway devices were prepared
14 and assembled before the start of the time measurements.

16 **Selection of Participants:**

17 We included only certified Swiss emergency physicians employed at the
18 Department of Anaesthesiology and Pain Therapy of Bern University Hospital who
19 also worked for the local helicopter-based emergency medical service or the local
20 ground emergency medical service (ambulance service). All participants were
21 practicing anesthesiologists and were as such trained in basic and advanced airway
22 management and familiar with all used devices. Participants were not specifically
23 trained beforehand to perform airway management in the isolation setting. This
24 reflects the clinical reality with large numbers of anesthesia providers and small
25 numbers of isolated patients, leading to providers having limited familiarity with
26 isolation equipment.

1 **Methods and Measurements:**

2 We compared the use of six different airway management techniques in each
3 of the three settings and tested the standard laryngoscope, two supraglottic airway
4 devices, two optical devices, and a cricothyrotomy set. Tracheal tubes of ID 7.0mm
5 were used with all intubation techniques. The following devices were used:

- 6 1) Macintosh blade for direct laryngoscopy
- 7 2) Airtraq™ SP video-laryngoscope (Teleflex®, Wayne, USA)
- 8 3) i-gel™ supraglottic airway device (Intersurgical, Wokingham, UK)
- 9 4) LMA Fastrach™ supraglottic airway device (Teleflex®, Wayne, USA)
- 10 5) Ambu® fiberoptic aScope™ (Ambu®, Copenhagen, Denmark)
- 11 6) Melker Emergency Cricothyrotomy Catheter Set (Seldinger) (Cook® Group
- 12 Incorporated Bloomington, USA). The cricothyrotomy was performed on a simplified
- 13 model as described by Varaday et al.¹¹ The model's "skin" and its "cricothyroid
- 14 membrane" were renewed after each attempt.

15
16 Primary outcome was the time in seconds from stopping bag-mask ventilation
17 until the first visible effective ventilation of the mannequin, measured by study
18 personnel not otherwise participating in the study.

19 One secondary outcome was the subjective rating of difficulty when handling a
20 device: After each device use, participants rated the level of difficulty on a 100mm
21 visual analogue scale (VAS), "0" representing "very easy" and "100" representing
22 "extremely difficult". After completion of all three settings, participants rated the
23 overall level of difficulty for each setting in the same way. Another secondary
24 outcome was the percentage of attempts that led to **successful ventilation in less than**
25 **60 seconds.**¹²

Data Analysis:

Assumptions for our sample size calculation were based on the results obtained in a study by Wang et al.⁴ Assuming a standard deviation of less than 20 seconds, 16 participants are required to detect a difference of 15 seconds with a power of 80% and an alpha error of 5%. We included 30 participants to compensate for dropouts.

The Shapiro-Wilk test was used to check the results for normal distribution. Not normally distributed data were analyzed by a generalized Friedman's test (Skillings-Mack test) to find differences in time-to-ventilate and subjective ratings of difficulties. Wilcoxon matched pairs signed-rank test was used to compare two settings at a time with a Bonferroni correction factor for multiple comparisons (PIU vs. Standard, PIU vs. PPE und PPE vs. Standard). As a sensitivity analysis, data were also included in a mixed model analysis to discover differences in time-to-ventilate across the three settings for each device.

For the analysis of the subjective ratings of difficulty all data were used regardless of success or failure.

All data were analyzed using Stata (Stata V.14.0, StataCorp, College Station, TX, USA). Results are presented as median with interquartile range for non-parametric data or mean and standard deviation for parametric data. Success rates are presented as percentages. A probability of less than $p=0.05$ was considered as significant.

RESULTS

Eighteen attending anesthesiologists (mean age 43 years, standard deviation ± 7.6 , 22% females) and 12 residents (mean age 40 ± 7.7 , 8% females) participated in the study. Together, they performed six emergency airway management procedures in each of the three settings. This led to a total number of 540 attempts to establish a patent airway. Out of these 540 attempts, 32 (5.9%) were unsuccessful: 18 because participants aborted, 10 because of oesophageal intubation, and 4 because the time limit of 240 seconds was exceeded.

Table 2 provides the times to ventilation (the primary outcome) and the overall success rates for each device in each setting. Comparing the different isolation scenarios, the generalized Friedman test revealed that time-to-ventilation differed significantly across the three settings ($p < 0.01$). No significant difference in time-to-ventilation was found between the standard and the PPE setting, but they were significantly longer in the PIU setting.

Comparing the different airway management devices, placement of supraglottic airway devices was fastest, followed by direct laryngoscopy, whereas the cricothyrotomy and the fiberoptic scope took longest to secure ventilation in all settings. When using the fiberoptic scope in the PIU, time-to-ventilate was more than three times longer compared to the standard setting (170 vs. 44 seconds). The cricothyrotomy took about 1.5 times longer in the PIU than within the standard setting (78 vs. 52 seconds).

Overall, 409 (76%) of airway management attempts were successful in < 60 seconds (overall median time-to-ventilate 26 (12-51) seconds), with marked differences between the settings (86% and 85% attempts were successful in the standard and PPE setting, respectively, while only 69% attempts succeeded within 60 seconds using the PIU; $p < 0.01$). In the standard setting, 86% of attempts to

1 ventilate were successful in <60 seconds (median time 23 (11-45) seconds). In the
2 PPE setting, this was the case in 85% (median time of 25 (11-48) seconds).
3 However, only 69% of attempts were completed in <60 seconds in the PIU setting
4 (38 (15-72) seconds (Table 1)).

5 The subjective ratings of difficulty for the three settings were highly different
6 between each setting ($p<0.01$) and for any of the airway devices significantly higher
7 in the PIU setting ($p<0.01$, Table 3 and Figure 4). Of the airway management
8 techniques, the fiberoptic scope was rated the most difficult (VAS 98 (87-100)),
9 followed by the Airtraq video laryngoscope (VAS 69 (48-75)). The supraglottic airway
10 devices were rated easiest in all three settings. There were no differences in
11 significances when using a mixed model instead of the generalized Friedman's test
12 or Wilcoxon. We found no significant differences in the time-to-ventilate or in the
13 subjective levels of difficulty when comparing attending anesthesiologists with
14 residents.

DISCUSSION

In this randomized controlled study about the effect of different isolation settings on airway management on mannequins in a simulated setting, we found marked differences in time-to-ventilate between a portable isolation unit (which surrounds the patient) and wearing personal protective equipment (surrounding the anesthesiologist). We found no statistically significant differences, however, in time-to-ventilate intervals between standard protective measures and personal protective equipment and thus could not confirm that wearing PPE affects the time needed to establish a protocol airway as previously described elsewhere.^{3,13}

Although wearing PPE only minimally affected time-to-ventilation when compared to a standard setting, it was perceived as significantly more difficult. The main complaints expressed in comments by the participants while wearing the equipment were discomfort, heat, perspiration and, especially for participants wearing glasses, discomfort and interference caused by the head cover. Working with and handling of the protective equipment itself is difficult and the risk of cross-contamination is significant, especially during removal: In a simulation study, Myreen et al. described that during removal of PPE, contamination of healthcare professionals' skin or clothing occurred in 46% of cases.^{14,15}

The use of a PIU substantially reduces this risk of contamination because the patient is completely isolated from the environment, regardless of how many HCW are caring for the patient at the same time. Main complaints when using the PIU in our study were the standardized one-sized gloves (often either too big or too small) and decreased and limited visibility through the plastic shield.

This study tried to answer the question whether and how severely these limitations affect the performance of emergency medical procedures such as airway

1 management. We saw substantially longer time intervals to achieve proper
2 ventilation, significantly higher ratings regarding subjective difficulty and reduced
3 overall success rates with the PIU. Specifically, airway management with the
4 fiberoptic scope took much longer than with other isolation scenarios and had a
5 failure rate of 60%. We, therefore, do not recommend the use of fiberoptic scopes in
6 a PIU.

7 Performing cricothyrotomy in the PIU took longer than one minute (median 78
8 seconds), and significantly longer than with the other two settings. Published studies
9 showed similar time requirements for successful cricothyrotomy; in contrast, expert
10 opinion states that successful cricothyrotomy can be achieved in 40 seconds or less
11 in a cannot-ventilate cannot-intubate situation.¹⁶⁻¹⁸ Interestingly, participants in our
12 study required more than these 40 seconds to perform cricothyrotomy in any of the
13 three settings. A possible reason for this is the difference in techniques (Seldinger vs.
14 surgical) and that, different from the cited articles, our endpoint included connecting a
15 ventilation bag and the administration of a first breath.¹⁹ Apparently, the feasibility of
16 this last option to secure oxygenation in a cannot-ventilate cannot-intubate situation
17 is limited in a PIU compared to when one has direct contact with the patient.

18 Excluding the fiberoptic scope and the cricothyrotomy from the initial analysis,
19 the success rates for successful intubation in less than 60 seconds in the PIU
20 scenario changed considerably from the initial 69% to 90%. This suggests that with
21 the exception of those two techniques, airway management in a PIU is possible
22 within clinically acceptable times.

23 The most reliable devices in both the PPE and PIU settings were supraglottic
24 airway devices, as the average time-to-ventilation was only about 14 seconds.
25 These times were even shorter in the standard setting (difference of about 5
26 seconds), but this is of doubtful clinical relevance. Our findings suggest that

1 supraglottic devices are a suitable option in the PIU setting. The marked differences
2 in times between the groups might be of clinical relevance when securing the airway.
3 In the PIU setting, we would refrain from using fiberoptic scopes even if airway
4 management is expected to be difficult. Direct laryngoscopy may be attempted by
5 sufficiently trained personnel; however, supraglottic airway devices should be readily
6 available and are likely to produce high success rates within seconds.

7
8 The mannequin design of this study limits generalization as results may or
9 may not be translatable into clinical practice. For one thing, the texture of the human
10 oropharynx is hard to recreate in mannequins. Moreover, mannequins are unable to
11 mimic the difficulties surrounding airway management in the presence of secretions
12 or blood in the airway. However, creating a real life scenario is difficult due to ethical
13 considerations, and we think that our results provide insight into the objective
14 feasibility and subjective impression of the difficulty surrounding the different
15 protective measures and their influence on emergency airway maneuvers.

16
17 In summary, this randomized controlled mannequin study demonstrates the
18 feasibility of performing airway management while wearing PPE even if participants
19 rated the procedure more difficult than under normal circumstances. Furthermore, we
20 showed that, with the exception of fiberoptic intubation and cricothyrotomy,
21 emergency airway management is quickly achievable even in a PIU. Supraglottic
22 airway devices remain highly recommendable if airway management is needed
23 during transport of a contagious patient in such an isolation device.

1 **ACKNOWLEDGMENTS**

2
3 **Prior Presentations:** The results of this study were previously presented, in part, at the
4 *Euroanaesthesia Congress* (ESA) in London, England, in May 2016 as well as at *EUSEM* in
5 Vienna, Austria, in October 2016.

6
7 **Author Contributions:** EP is the first author. LT, EP, RA, MKB and RG conceived the study,
8 designed and supervised the conduct of the trial. EP, TP, LT were in charge of data
9 collection and recruitment of participants. EP, LT, JM, RG, MKB analyzed the data and
10 drafted the manuscript. All authors contributed to the final version and approved the
11 manuscript.

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13 The listed authors state that no financial or any other conflict of interests exists.

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15 Anaesthesiology & Pain Medicine, Inselspital, Bern University Hospital, University of Bern,
16 Bern, Switzerland.

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Figures:

Figure 1: Personal protective equipment (PPE)

Figure 2: Mannequin isolated in portable isolation unit (PIU)

Figure 3: Overall subjective rating of difficulty. Numbers are median (IQR).

1 Table 1: Success rates and times-to-ventilate

2

	Overall	Direct laryngoscopy	Airtraq	i-gel	ILMA Fastrach	Fiberoptic scope	Cricothyrotomy	Ventilation <60sec
Standard								
Time to ventilate	23 (11-45)	23 (19-29)	26 (21-36)	9 (7-10)	9 (7-11)	44 (32-56)	52 (46-72)	
Success rate	179/180 99%	30/30 100%	29/30 97%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	154/179 86%
PPE								
Time to ventilate	25 (11-48)	24 (20-29)	29 (23-48)	10 (8-11)	10 (8-12)	51 (40-88)	58 (45-69)	
Success rate	175/180 97%	30/30 100%	27/30 90%	30/30 100%	30/30 100%	28/30 93%	30/30 100%	148/175 85%
PIU								
Time to ventilate	38* (15-72)	41* (31-49)	51* (36-74)	13* (11-15)	15* (12-19)*	170* (126-210)	78* (63-101)	
Success rate	154/180 86%	28/30 93%	24/30 80%	30/30 100%	30/30 100%	12/30 40%	30/30 100%	107/154 69%#

3

4 [Time-to-ventilate (seconds), median (IQR)]

5 [Success rate (successful attempts / total number of attempts)]

6 [Ventilation < 60sec (successful attempts < 60sec / successful attempts)]

7 [*significantly different to PPE and standard setting (Wilcoxon matched pairs signed-rank test p< 0.02, Bonferroni correction factor)]

8 [#significantly different to PPE and standard setting (Two-sample test of proportions, p<0.05)]

9

10

1 Table 2: Subjective rating of difficulty per setting and device

<i>n=540</i>	Overall settings' rating	Direct laryngoscopy	Airtraq	i-gel	ILMA Fastrach	Fiberoptic scope	Cricothyrotomy
Standard	9*(5-13)	16 (8-27)	29 (14-52)	3 (0-8)	2 (0-6)	25 (14-37)	20 (13-37)
PPE	35*(26-51)	19 (12-32)	38 (16-50)	6 (2-15)	7(1-12)	38 (23-49)	24 (14-42)
PIU	76*(68-84)	63*(47-75)	69*(48-99)	20*(7-26)	20*(10-31)	98*(87-100)	58*(43-70)

2

3 [Subjective level of difficulty (0-100mm VAS), median (IQR)]]

4 [*significantly different to the other two settings (Wilcoxon matched pairs signed-rank test $p < 0.01$, Bonferroni correction factor)]

5

6

7