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1.1 Author information

Richard Pilbery
Research paramedic
Yorkshire Ambulance Service NHS Trust
Springhill, Brindley Way
Wakefield 41 Business Park
Wakefield
WF2 0XQ

ORCID: https://orcid.org/0000-0002-5797-9788

email: r.pilbery@nhs.net
tel:

Word count: 1684

Keywords: Keyword 1, keyword 2, keyword 3

1.2 Abstract

1.2.1 Introduction

Intro

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2 Introduction

Vomiting and regurgitation are commonly encountered in out-hospital-cardiac arrest with a reported incidence of 20–30% (Voss et al., 2014; Simons et al., 2007). This is of concern since patients who have suffered an OHCA, are already in extremis. If standard suctioning techniques are not sufficient to maintain a clear airway and provide ventilation, then these patients will die, irrespective of the quality of chest compressions and the timeliness of defibrillation. Arguably, tracheal intubation is the preferred airway management technique in patients with ongoing airway contamination, but there is evidence that this is difficult to achieve when the airway is soiled (Sakles et al., 2017). Even if patients survive to the hospital, it is possible that aspiration pneumonias may adversely affect survival outcome, although this has yet to be proved empirically (Christ et al., 2016).

Traditional suctioning techniques have been criticised, and training in the management of contaminated airways, limited. This has led to the development of a combined suction/laryngoscopy technique to facilitate intubation, known as Suction Assisted Laryngoscopy and Airway Decontamination (SALAD), and the creation of modified airway manikins to allow for practice in these techniques (DuCanto et al., 2017).

However, to date there has only been one study specifically looking at the SALAD technique and the outcomes were self-reported confidence measures of trainees in using the technique. Other techniques have been described to manage significant airway contamination, including the use of a meconium aspirator (Kei and Mebust, 2017), which is not practical in the out-of-hospital environment (and requires a device that is not typically carried by UK ambulance services), and deliberate intubation of the oesophagus (the oesophageal diversion manoeuvre), of which the sum total of evidence in support of the procedure is a single case report (Kornhall et al., 2015).

This study aims to determine whether a short teaching session of the SALAD technique to paramedics, improves their ability to intubate a contaminated airway.The primary objective is to determine the difference between paramedic first-pass intubation success, before and after SALAD training, in a simulated soiled airway. Secondary objectives are to determine the difference in time taken to achieve first-pass intubation success, before and after SALAD training in a simulated soiled airway, and the effect of multiple intubation attempts on success rates following SALAD training.

3 Methods

3.1 Study design and participants

This randomised controlled trial was conducted in Yorkshire Ambulance Service NHS Trust (YAS). Participants were NHS staff employed by YAS, who were Health and Care Professions Council (HCPC) registered paramedics at the time of enrolment in the study, authorised to intubate and who had received no SALAD training in the previous 3 months. Potential participants were excluded if they did not meet the inclusion criteria, were allergic to the 'vomit' ingredients or unwilling to provide consent to participate.

3.2 Randomisation

In order to adjust for changes in participant performance by making repeated attempts at intubation, paramedics were randomised into either: making two pre-training intubation attempts and one post-training attempt (group AAB); or making one pre-training intubation attempt and two post-training attempts (ABB). Groups were evenly allocated (i.e. 1:1) using a block randomisation sequence provided by RANDOM.ORG. To distinguish between the training pathways and number of the assessed attempts, group AAB's attempts were denoted $A_{01}A_{02}B_{01}$ and group ABBs, $A_{11}B_{11}B_{12}$. It was not possible to blind participants or the researcher from the group allocation.

3.3 Intervention

3.3.1 SALAD manikin

A modified TruCorp AirSim Advance airway manikin was used for the study as it has realistic airway anatomy and can be used for tracheal intubation training. The oesophagus of this manikin has been connected, via a hosepipe, to a bilge pump that is sited within a reservoir of simulated vomit (Figure 1). The vomit is water, coloured with food-grade colouring, and thickened with xanthan gum (a food additive). Once the bilge pump is switched on, it can generate a constant flow of liquid into the oropharynx, obscuring any view of the laryngeal inlet. The flow rate is controlled by a tap, which was calibrated to provide 1 L/min of vomit to the oropharynx of the manikin during intubation attempts. To keep vomit within the oropharynx, the left and right bronchi on the manikin have been occluded.

Standard intubation equipment, including personal protective equipment (PPE) and motorised suction, that is routinely used within YAS was provided for participants, and the study researcher acted as a competent assistant for the intubation attempts.

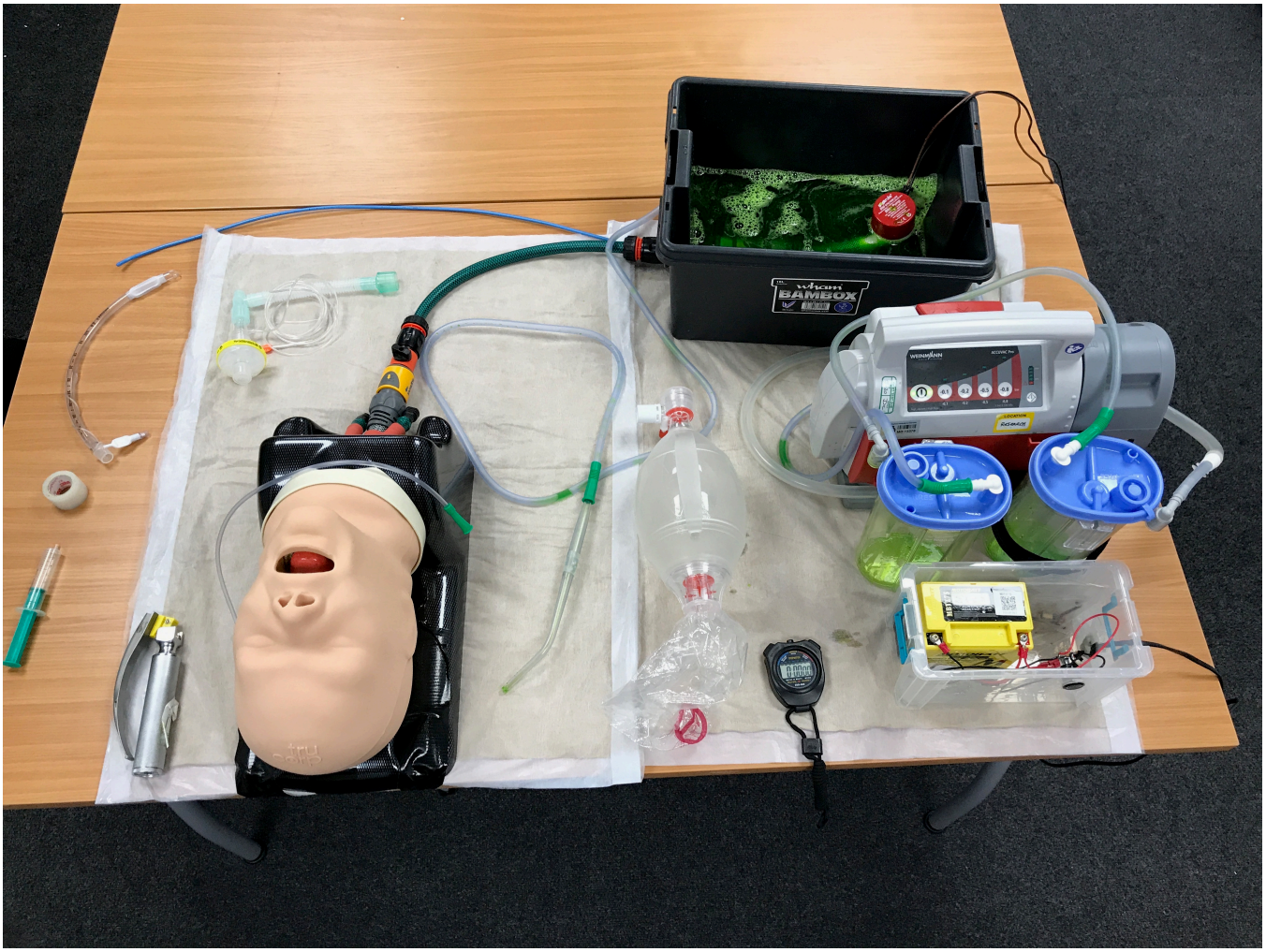

Figure 1: SALAD manikin setup used for the study

3.3.2 Procedure

Once informed consent was obtained, paramedics were randomised into either group AAB or ABB. All attempts utilised direct laryngoscopy, which is the standard intubation technique within YAS. Prior to each intubation attempt, the manikin was primed with vomit to ensure the same level of oropharyngeal obstruction. All attempts were video recorded for timing accuracy.

Participants were deemed to have begun their attempt once the bilge pump was turned on. The attempt will be considered over when either: the paramedic intubates the manikin and verbally confirms with the researcher that the attempt has been completed or; 90 seconds has elapsed or; the tracheal tube is placed into the oesophagus and the cuff is inflated while the pump is still running.

If the tracheal tube was not in the trachea, with the cuff inflated and connected to a bag-valve device within 90 seconds, the attempt was considered a failure.

Participants randomised into the two pre-training attempts group (AAB) made their second intubation attempt immediately following the first, and prior to the group training session. Once all participants completed their pre-training intubation attempt(s), the training session was delivered. The training intervention adopted the Advanced Life Support Group/Resuscitation Council 4-stage approach of skills teaching, comprising (Bullock et al., 2008):

1. A real-time demonstration of the SALAD technique by the researcher
2. A repeated demonstration with an explanation of the rationale of the steps taken when performing SALAD (not real-time)
3. Another demonstration of the SALAD technique conducted by the researcher, but guided by one of the participants
4. An attempt by the same participant who guided the researcher in the previous step, followed by a practice attempt by the other participants.

Following the training session, participants made their post-training intubation attempt(s) conducted using the same method as for the pre-training intubation attempt(s). Participants randomised into the two post-training attempts (ABB), made their second attempt immediately following the first post-training attempt.

3.4 Outcomes

The primary outcome is the difference in proportions of paramedic first-pass intubation success, before and after SALAD training The secondary outcomes are:

- Mean of the differences in intubation attempt times, between first and second intubation attempts, and between pre- and post-training attempts
- Difference in success rates between participants who have two post-training intubation attempts versus participants who only have one post-training intubation attempt.

3.5 Statistical analysis

3.6 Sample size

A sample size of 154 participants was calculated to be required to determine a change in the proportion of intubation success, from 0.25 in the pre-training group, to 0.50 in post-training group, with a power (1-β) of 90% and a significance level (α) of 5%. Given that there is no literature to guide expected performance, a conservative estimate was made in consultation with an internationally recognised SALAD expert, Dr. James DuCanto (J.DuCanto, personal communication, April 26, 2018).

3.6.1 Primary outcome analysis

To determine if the training has an effect and increases the success rate of intubation, the proportions of success in the groups who received no training before their 2nd intubation attempt (A_{02}) was compared to those who did receive training before their 2nd intubation attempt (B_{11}). Comparing the rates at these time points, controls for

Table 1: Summary details of participants

Measure	AAB	ABB	Total
n	82	82	164
Median intubation attempts in past 12 months (IQR)	2.5 (0-6)	3.0 (1-7)	3.0 (1-6.5)
Median number of successful intubation attempts in past 12 months (IQR)	2 (0-5)	2 (0-6)	2 (0-6)
Median years as paramedic (IQR)	5.0 (1-10)	3.5 (0-10)	4.0 (1-10)
Familiar with SALAD technique	15	21	36

Table 2: Summary data of successful intubation attempts

	Attempt 1		Attempt 2		Attempt 3	
Measure	AAB	ABB	AAB	ABB	AAB	ABB
Successful attempts n (%)	29 (35.4)	31 (37.8)	44 (53.7)	74 (90.2)	71 (86.6)	73 (89)
Median elapsed time to intubation attempt secs (IQR)	7 (4–13)	6 (3–11)	4 (2–8.5)	4 (2–6)	4 (2–5.5)	3 (2–5)
Median intubation attempt time secs (IQR)	54 (46–61)	50 (40.5–58.5)	40.5 (32.5–57.5)	44 (39–53)	47 (40–54)	41 (35–50)
Median total attempt time secs (IQR)	63 (52–74)	59 (48.5–70.5)	49 (37.5–61.5)	47.5 (43–58)	51 (43.5–58)	44 (38–52)

any learning effect due to participants making more than one attempt at intubation. The difference in the two proportions was analysed using a two independent samples proportion z-test, assuming a two-sided type 1 error rate of 5%.

3.6.2 Secondary outcome analysis

Intubation times were truncated at 90 seconds. The mean of the differences (A_{01} – A_{02}) were compared with the mean of differences (A_{11} – B_{11}). The mean of the differences seen at the final measurements, (A_{01} – B_{01}) were compared to (A_{11} – B_{12}), to see if there were any differences between the two pathways, which might suggest that practice following the training, further improves the time to successful intubation. In addition, success rates between B_{01} and B_{12} attempts were compared to see whether practice following training improved intubation success rate. A Student's t-test was utilised to test for the differences between mean pre- and post-training intubation attempt times, and a two independent samples proportion z-test to test the difference in success rates.

4 Results

164 participants took part in SATIATED, with an equal number in groups AAB and ABB. The groups were similar with respect to intubation attempts (successful or not) undertaken in the previous 12 months. The median number of years as a paramedic was 1.5 years less in group ABB, although the interquartile range was similar. 36 participants had heard of the SALAD technique prior to the study, with a slightly higher number in group ABB (Table 1).

First-pass intubation success with and without SALAD was 53.7% vs 90.2% respectively, a significant difference of 36.6% (95%CI 24–49.1%, p=0.00).

Figure 2 summarises the intubation attempt times by participants in each randomisation sequence. The time to successful intubation for each attempt, stratified by randomisation sequence can be seen on Table 2, and

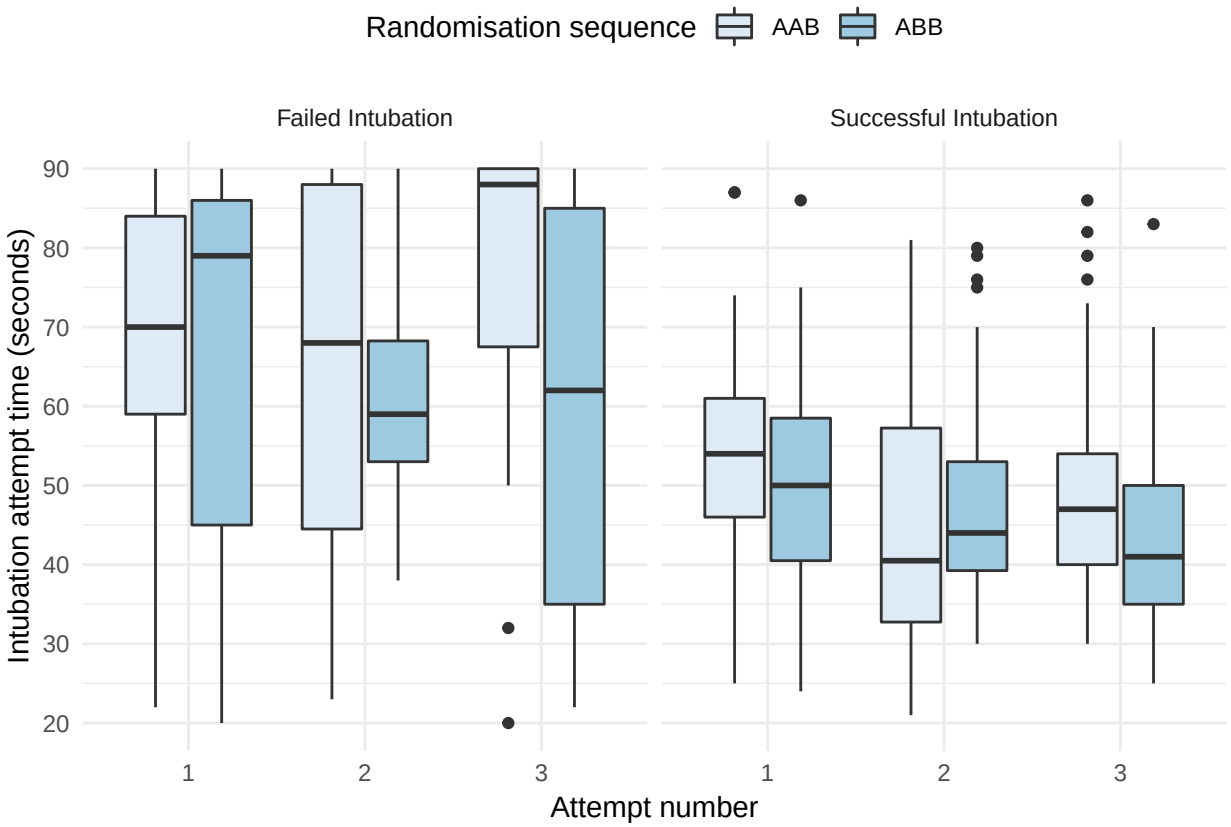

Figure 2: Intubation attempt times, stratified by randomisation sequence and intubation success

4.0.1 Mean difference in successful intubation attempts

There was a significant difference between groups AAB (n=23) and ABB (n=28) with respect to the mean difference in time taken to perform a successful intubation on attempts 1 and 2 (mean difference 11.71 seconds, 95% CI 1.95–21.47 seconds, p=0.02). There was no significant difference between groups AAB (n=27) and ABB (n=27) with respect to mean difference in time taken to perform a successful intubation on attempts 1 and 3 (mean difference -2.52 seconds, 95% CI -11.64–6.61 seconds, p=0.58)). Summary values for the mean differences are shown in Table 3.

There was no significant difference in success rates on the third attempt between AAB and ABB 89% vs 86.6% respectively, a difference of 2.4% (95%CI 7.6–12.4%, p=0.63).

Table 3: Summary data of successful intubation attempts

group	n	mean difference (secs)	standard deviation (secs)	standard error (secs)	95% CI
Attempts 1 and 2					
AAB	23	15.4	16.7	3.5	8.2–22.6
ABB	28	3.7	17.9	3.4	-3.3–10.6
Attempts 1 and 3					
AAB	27	6.0	20.4	3.9	-2.1–14.1
ABB	27	8.5	11.5	2.2	4–13.1

4.0.2 Other stuff

- Bougie use
- suction down tube
- Assistant hold bougie
- Oesophageal intubations
- Suction left in situ
- Hole not occluded

5 Discussion

Discussion blurb

6 Conclusion

The conclusion

7 Appendix A

Appendix (if you need one)

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