

## Research

# Soiled airway tracheal intubation and the effectiveness of decontamination by United Kingdom paramedics (SATIATED2): A randomised controlled manikin study

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## Abstract

### Introduction

Vomiting and regurgitation are commonly encountered in out-of-hospital cardiac arrest, but traditional paramedic suctioning techniques may be insufficient to manage severely soiled airways. The Suction Assisted Laryngoscopy and Airway Decontamination (SALAD) technique was developed to help clinicians manage soiled airways. SATIATED2 reports the impact of SALAD training in North East Ambulance Service (NEAS) in the United Kingdom following the original SATIATED study in the Yorkshire Ambulance Service.

The primary research question was: Among NEAS paramedics, does the addition of SALAD training, compared to standard training, improve the success rate of intubation for the soiled airway?

### Methods

A randomised controlled trial of SALAD was conducted using a modified airway manikin capable of vomiting. The intervention comprised SALAD training and the introduction of the DuCanto catheter. Paramedic volunteers were block randomised into two groups:  $A_{01}A_{02}B_{01}$  who made two pre-training intubation attempts and one post-training attempt, and  $A_{11}B_{11}B_{12}$  who made one pre-training and two post-training attempts. The primary outcome was intubation success rate at the second attempt. The time taken to intubate was recorded as a secondary outcome. SATIATED2 was registered with ISRCTN (ISRCTN17329526) and funded internally with commercial support from SSCOR who supplied the DuCanto catheters.

### Results

One-hundred and two paramedics (51 AAB, 51 ABB) were recruited between August and December 2019 with 99 participating (50 AAB, 49 ABB). The primary outcome was intubation success rate on the second attempt ( $A_{02}$  vs.  $B_{11}$ ) which were 86% without SALAD and 96% with SALAD; a non-significant improvement of 10% (95% CI: 1–21,  $p=0.09$ ). The total intubation success rate pre-training ( $A_{01}+A_{02}+A_{11}$ ) was 75% (112/149) compared with 98% (145/148) post-training ( $B_{01}+B_{11}+B_{12}$ ).

### Conclusion

NEAS paramedics demonstrated improved, but non-significant, intubation success rates in a simulated soiled airway following SALAD training.

Keywords:

paramedic; intubation; suction; SALAD

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## Introduction

Airway management is a vital skill for pre-hospital clinicians and a topic of constant debate in the paramedic profession (1) with the conversation sustained by the recent AIRWAYS2 trial (2) and the removal of intubation by some United Kingdom ambulance services.

Dealing with airways filled with vomit is one of the challenges faced by paramedics (3). Conditions such as drowning, major facial trauma and out-of-hospital cardiac arrests (OHCA) may require clinicians to manage a soiled airway. Airway soiling from vomiting and regurgitation are reported in 20–30% of OHCA (2,4,5). While severe airway soiling is uncommon, 44% of pre-hospital intubations have been reported to be contaminated with blood, vomit or other material (6). If management is not rapid and effective in patients with a soiled/occluded airway, then the patient's prognosis is poor (4).

Concern about clinicians' ability to manage severely soiled airways led to the development of a combined suction and laryngoscopy technique to facilitate intubation. The technique is called Suction Assisted Laryngoscopy and Airway Decontamination (SALAD), and modified airway manikins have been developed to allow for practise of the technique (7). The SALAD technique is clearly described in the papers by Pilbery and Teare (8) and Ko et al (9) and many videos demonstrating SALAD can be found online.

The first SALAD study in a UK National Health Service (NHS) ambulance service was the SATIATED study (8) conducted in Yorkshire Ambulance Service NHS Trust (YAS). SATIATED investigated the effectiveness of training paramedics in the SALAD technique on intubation success rates and the time to intubation. SATIATED reported a 36% improvement in their primary outcome which was intubation success rate.

In order to expand the evidence base for SALAD in a UK setting, the study was replicated in North East Ambulance Service NHS Foundation Trust (NEAS). Replication of studies is necessary to increase generalisability and confidence in results (10,11).

## Aim

This study aimed to determine whether the SALAD technique improved the ability of NEAS paramedics to intubate a soiled airway.

### Research questions

The primary research question was: Among NEAS paramedics, does the addition of SALAD training, compared to standard training, improve the success rate of intubation for the soiled airway? The secondary research question was: Does training in SALAD affect the time taken to successfully intubate a soiled airway by NEAS paramedics?

## Objectives

The primary objective was to determine the difference between paramedic intubation success, before and after SALAD training, in a simulated soiled airway. The secondary objective was to determine the difference in time taken to achieve intubation success, before and after SALAD training in a simulated soiled airway.

## Methods

SATIATED2 was a randomised controlled trial that replicated the methods of the original SATIATED study (8,12). The methods are briefly summarised and the differences between the two studies identified.

SATIATED2 was conducted in the NEAS, a UK regional ambulance service covering 2.7 million people. NEAS is the northern neighbour of YAS, both of whom are part of the Northern Ambulance Alliance.

All participants were volunteer NEAS paramedics who met the same criteria as the SATIATED study. The inclusion criteria were age more than 18 years; Health and Care Professions Council registered paramedic; authorised to intubate. The exclusion criteria were SALAD training within 3 months and allergy to fake vomit ingredients. SATIATED2 study sessions were advertised via internal email, weekly newsletters, social media and word-of-mouth and paramedics were asked to contact the researcher if they wished to participate.

### SATIATED2 study sessions

Volunteers were given the participant information sheet to read and asked to sign a consent form at the start of the session after they had an opportunity to ask any questions.

Participants were sequentially 1:1 randomised after informed consent, using a block randomisation sequence pre-generated by RANDOM.ORG, to either two pre-training and one post-training attempts ( $A_{01}, A_{02}, B_{01}$ ) or one pre-training and two post-training attempts ( $A_{11}, B_{11}, B_{12}$ ).

SATIATED2 study sessions involved: obtaining informed consent; individual pre-training intubation assessments; SALAD training as a group; and individual post-training intubation assessments.

All volunteers who completed the study were given a £5 Amazon voucher as a token of appreciation.

### The SALAD manikin

The study manikin was a modified Laerdal Airway Management Trainer (Laerdal Medical Ltd, UK). The manikin's oesophagus was connected, via a hosepipe, to a bilge pump sited within a reservoir of simulated vomit. The fake vomit comprised water, green food colouring, xanthan gum as a thickener and vinegar.

The bilge pump produced a constant flow of vomit which could be adjusted using a valve. The flow rate was set to 1 litre per minute and calibrated at the start of each session by measuring the volume of vomit over 1 minute. The manikin and vomit were based on the methods described in the original SALAD paper by DuCanto (7).

### **Intubation attempts**

Each participant had three assessed intubation attempts using direct laryngoscopy. Standardised NEAS intubation equipment (laryngoscope with size 3 blade; bag valve mask; catheter mount; size 7 endotracheal tube; hard and soft suction catheters; bougie), gloves and facemasks and powered suction used within NEAS (SSCOR VX-2 Portable Suction, SSCOR Inc, USBVM) were provided for all participants which they could arrange as they chose. The researcher acted as an assistant for the intubation attempts.

Each attempt was video recorded for data collection purposes, with a stopwatch used as a backup. The attempt started once the manikin was filled with vomit to the level of the back molar. The manikin vomited continuously during each attempt. The intubation attempt was considered complete when the paramedic ventilated the manikin using a bag valve mask connected to the endotracheal tube, 90 seconds had elapsed or the paramedic decided they were unable to intubate the manikin.

To be considered a successful attempt, the endotracheal tube needed to be in the trachea, with the cuff past the vocal cords and inflated within 90 seconds. The 90-second time limit mirrored the original SATIATED study and was selected to put the participants under some pressure. Successful placement was visually checked by the researcher following each attempt.

### **SALAD training**

The SALAD training session was delivered to the participants in a group after the pre-training attempts and followed the same four-stage Advanced Life Support Group/Resuscitation Council (13) format as the SATIATED study: SALAD demonstration by researcher in real time; SALAD demonstration by researcher broken down step-by-step; demonstration of SALAD guided by participants and researcher; participant attempts and practice.

Training took about 1 hour in most cases. Once participants indicated they were confident with the SALAD technique, the post-training assessed intubation attempts were completed using the same scenario as the pre-training attempts.

While conceptually and procedurally like the SATIATED study, there were differences in SATIATED2: different airway heads (SATIATED utilised a TruCorp AirSim Advance (TruCorp AirSim Advance Adult Airway Management Training Manikin, TruCorp, Northern Ireland)); SATIATED2 included vinegar in the vomit; the standard rigid suction catheter used within NEAS does not have a side port that needed occluding whereas the YAS

version did have a side port; the DuCanto suction catheter was introduced during the SALAD training and used for post-training attempts in SATIATED2; time to suction of the endotracheal tube was recorded in SATIATED2 after being identified as a difference between pre- and post-training attempts in SATIATED.

The DuCanto catheter was introduced in this study as an adjunct for the SALAD technique which it facilitates due to the slightly different angle and larger bore.

### **Sample size calculation**

An increased (but conservative) estimate of intubation success based on the results from SATIATED was chosen to calculate the sample size. Thus, to determine a change in the proportion of intubation success from 0.35 in the pre-training group to 0.70 in post-training group, with a power  $(1-\beta)$  of 90%, a significance level  $(\alpha)$  of 5% and 1:1 randomisation, a sample size of 82 was required. The target was rounded to 100 due to the low risk and the potential for participants to drop out.

### **Statistical analysis**

Descriptive statistics are used to summarise the participant demographics, baseline data and flow of patients which were calculated in the statistics package R (R Core Team).

### **Primary outcome analysis**

The primary outcome compares success rates in participants who received no SALAD training before their second intubation attempt ( $A_{02}$ ), with participants who received SALAD training before their second intubation attempt ( $B_{11}$ ). This was to control for any learning effect due to the participants making multiple intubation attempts and was analysed using a two independent samples proportion z-test, assuming a two-sided type 1 error rate of 5%.

### **Secondary outcome analysis**

Mean pre- and post-training intubation attempt times were compared using a student's t-test. Intubation times were also compared in a similar fashion to SATIATED with the mean of the differences between the first two AAB attempts ( $A_{01}-A_{02}$ ) compared with the mean of the differences between the first two ABB attempts ( $A_{11}-B_{11}$ ). The mean of the differences between first and last attempts in each group are also compared.

### **Procedure to account for missing data**

If the video recording failed, then the stopwatch recorded outcomes were used. Participants who failed to complete all three intubation attempts were excluded from the final analysis.

### **Peer review**

This study was reviewed within NEAS by the research and development department. The study was presented to a patient panel (the North East Healthwatch group) in April 2019 who were supportive of the study.

## Ethical and regulatory considerations

Research Ethics Committee review was not needed for this trial as it was a staff-based study. NEAS Research and Health Research Authority approvals were secured (IRAS ID 259844). SATIATED2 was adopted onto the NHS portfolio (CPMS ID 42102) and registered on the ISRCTN registry (study ID ISRCTN17329526).

## Results

Between 6 August 2019 and 1 December 2019, 102 paramedics (51 AAB, 51 ABB) participated in the study by attending one of the 18 study sessions. Technical issues with the manikin during one session meant the participants (n=3) were unable to complete the study and were removed from the analysis.

Ninety-nine participants completed the study and are described in Table 1. 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 the same. Sixteen (16%) participants had heard of the SALAD technique before the study, with a slightly higher number in

group ABB.

### Primary outcome: difference between paramedic intubation success, before and after SALAD training

Intubation success on the second attempt was 86% (43/50) without SALAD ( $A_{02}$ ) and 96% (47/49) with SALAD ( $B_{11}$ ), a non-significant difference of 10% (95% CI: 1–21%,  $p=0.09$ ).

The total intubation success rate pre-training ( $A_{01}+A_{02}+A_{11}$ ) was 75% (112/149) compared with 98% (145/148) post-training ( $B_{01}+B_{11}+B_{12}$ ).

The reasons for unsuccessful intubations (n=40) were: 73% ran out of time; 20% endotracheal tube cuff was outside vocal chords; and 8% oesophageal intubation.

### Secondary outcome: difference in time to successful intubation

Figure 1 summarises the median intubation attempt times by participants in each randomisation group. Mean time to intubation was compared for successful attempts pre- and post-SALAD training and showed a reduction of 1.6 seconds post-training which was non-significant (t-test, statistic -0.93, df 200.23,  $p=0.35$ ). Table 2 reports the intubation attempt timings and includes the time to suction of the endotracheal tube.

Table 1. Summary of participants and intubation success rates

Measure	AAB	ABB	Total
Participants	50	49	99
Median intubation attempts in past 12 months (IQR)	1.5 (0-2)	1.0 (0-3)	1.0 (0-2)
Median number of successful intubation attempts in past 12 months (IQR)	1.0 (0-2)	1.0 (0-2)	1.0 (0-2)
Median years as paramedic (IQR)	8.5 (3-13)	7.0 (3-13)	7.0 (3-13)
Familiar with SALAD technique (%)	7 (14)	9 (18)	16 (16)
Attempt 1 intubation successes (%)	33 (66)	36 (73)	69 (70)
Attempt 2 intubation successes (%)	43 (86)	47 (96)	90 (91)
Attempt 3 intubation successes (%)	50 (100)	48 (98)	98 (99)

Note: IQR = inter-quartile range; SALAD = suction assisted laryngoscopy and airway decontamination

Table 2. Intubation attempt summary data

Measure	Intubation attempt					
	$A_{01}$	$A_{02}$	$B_{01}$	$A_{11}$	$B_{11}$	$B_{12}$
Successful attempts n (%)	33 (66)	43 (86)	50 (100)	36 (74)	47 (96)	48 (98)
Median intubation attempt time seconds (IQR)	60 (56-73)	49 (44-60)	60 (54-63)	66 (53-76)	57 (50-66)	54 (48-63)
Endotracheal tube suction before ventilation n (%)	0	0	48 (96)	0	46 (98)	47 (98)
Median time to suction of the endotracheal tube seconds (IQR)	NA	NA	46 (42-50)	NA	44 (39-49)	39 (37-48)

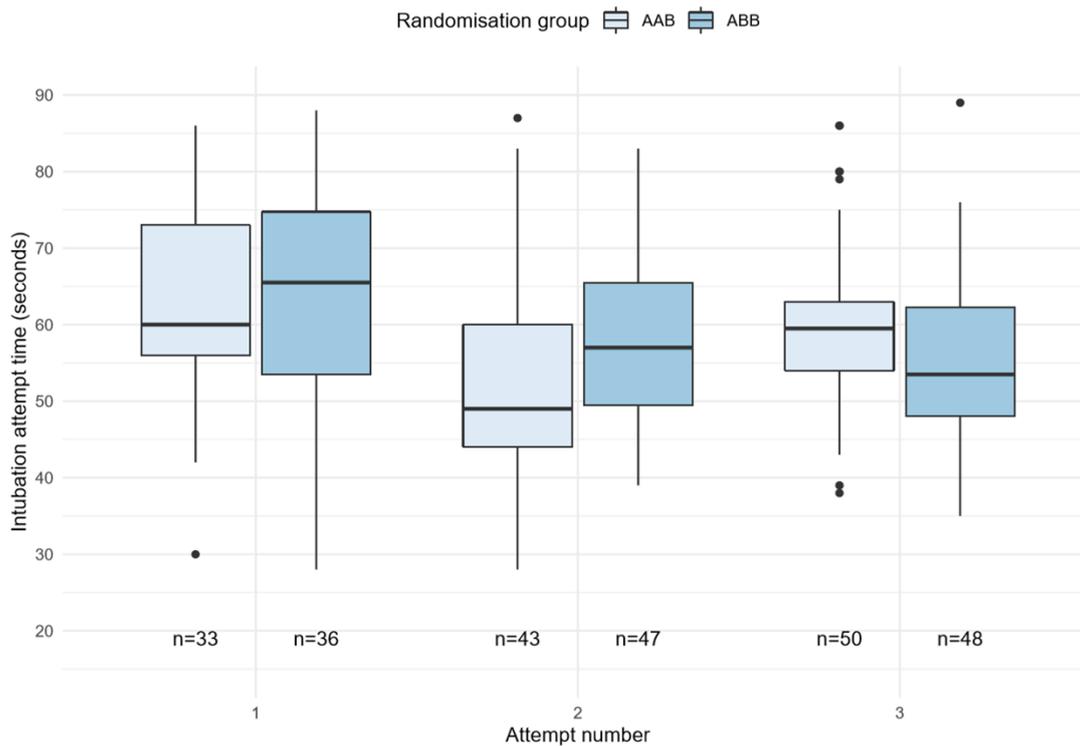


Figure 1. Median successful intubation attempt times, stratified by randomisation sequence and attempt

To determine the mean difference in time to successful intubation, a subset of the data comprising participants who successfully intubated on attempts 1 and 2, and attempts 1 and 3, was examined.

There was a statistically significant difference between groups AAB (n=31) and ABB (n=34) with respect to the mean difference in time taken to perform a successful intubation on attempts 1 and 2 (mean difference 8.54 seconds, 95% CI: 2.54–14.53 seconds, p=0.01). There was no significant difference between groups AAB (n=33) and ABB (n=35) with respect to mean difference in time taken to perform a successful intubation on attempts 1 and 3 (mean difference -4.41 seconds, 95% CI: -11.47–2.65 seconds, p=0.22). Summary values for the mean differences are shown in Table 3.

### Intubation techniques

A bougie was used for 98% (n=290/297) of all intubation attempts. Intubation was 57% (n=4/7) successful when a

bougie was not used. A range of airway management and intubation support techniques used by participants are summarised along with the number of attempts where this was used: pre-loading syringe/catheter mount (n=27); postural drainage (n=7); cricoid pressure (n=6); soft suction for whole attempt (n=3); bare suction tubing (n=2); and D-grip on bougie (n=1).

## Discussion

This study demonstrated that SALAD training improved the intubation success rate, although not statistically significantly, and slightly reduced the time to intubation in a simulated soiled airway. The reduction in time was not statistically significant but 97% of participants suctioned the endotracheal tube post-SALAD training whereas no participants did this before training. SATIATED2 supports the findings of the SATIATED study and strengthens the evidence base showing that SALAD training is beneficial for paramedics.

Table 3. Successful intubation timing data

Group	N	Mean difference (seconds)	Standard deviation (seconds)	Standard error (seconds)	95% confidence interval
A <sub>01</sub> -A <sub>02</sub>	31	14.4	11.8	2.1	10.1-18.7
A <sub>11</sub> -B <sub>11</sub>	34	5.9	12.4	2.1	1.5-10.2
A <sub>01</sub> -B <sub>01</sub>	33	4.9	14.0	2.4	-0.1-9.8
A <sub>11</sub> -B <sub>12</sub>	35	9.3	15.2	2.6	4.1-14.5

## Results in context

SATIATED2 replicated the original SATIATED study with a few key differences which are described above. The baseline intubation success rate in SATIATED2 was higher than in SATIATED (86% vs. 54%) so the hypothesised 35% improvement was unachievable. The increased success rate seen in NEAS participants compared to YAS participants may be due to differences in the paramedic participants. NEAS paramedics were more experienced (median years qualified 7 vs. 4) although with less exposure to intubation. There were also differences in the equipment used, which may have influenced the success rate such as the higher bougie use in NEAS.

SATIATED2 agrees with the growing body of literature reporting improved ability to intubate soiled airways using the SALAD technique. The first published paper by DuCanto, Serrano and Thompson (7) described how SALAD training improved participants self-reported confidence in managing a difficult airway and reported positive feedback from the mixed group of learners. The SALAD technique, and an adapted SALAD technique involving deliberate oesophageal intubation to divert gastric contents, have been shown to be superior to conventional suction techniques when used by emergency department doctors in Hong Kong (9). A study involving American nurses and paramedics reported improved intubation success rates and reduced time to intubation following SALAD training (14) and sustained improvement at 3 months (15). SALAD was shown to improve intubation success rates and clinician confidence and reduce time to intubation in a Taiwanese study (16). An American study compared senior anaesthetists and emergency doctor use of SALAD with conventional management and intentional oesophageal intubation to control massive emesis and found all three produced similar results, so SALAD appears equivalent to other techniques used to manage soiled airways (17). The overall body of literature, although small and largely based on manikin studies, indicates that SALAD is a useful technique for dealing with a severely soiled airway.

## Sources of bias

There was no way to control participants' previous knowledge or exposure to SALAD and some participants were clearly familiar with the technique. The participants had a wide range of previous experience (0–40 intubations within previous 12 months) and lengths of service (1 month to 29 years) which impacted on performance.

## Transferability

Paramedic practice in the UK is standardised by the Joint Royal Colleges Ambulance Liaison Committee (18) guidelines and the small number of services. The results of this study should be transferable to other UK services, however, there are some regional variations in the equipment available to paramedics. Pre-hospital intubation is practiced by paramedics across the world although there are variations in training,

equipment and guidelines. The SALAD technique should be applicable in any ambulance service using intubating with adaptation based on local practice.

## Implications for practice and research

Whether paramedics should intubate is a topic that generates heated discussion by pre-hospital clinicians (3). The SALAD technique is aimed at an infrequent situation so may see most use by practitioners who are frequently intubating or dealing with unusual situations such as critical care teams. The SALAD technique is simple to teach, and the equipment can be cheaply built by modifying an existing airway manikin so there are few barriers to implementing SALAD training. Due to the simplicity of the SALAD technique and the potential benefit for a small group of patients the authors think that this is a valuable technique for paramedics to learn and practice. Consideration may need to be given to the cost in terms of material and time to maintain a skill like SALAD in addition to other practical paramedic skills. Further research could explore how SALAD performs in real clinical practice with a focus on paramedics who are frequently exposed to soiled airways.

## Limitations

This was a simulated manikin study so caution is needed drawing conclusions on how SALAD would work in real patients. Anecdotally, the authors have received reports of SALAD being used successfully in clinical practice following study participation. The primary outcome, difference in intubation success rates, was not statistically significant but the trend towards improvement is clear. Participants used a range of intubation techniques reflecting individual practice which could be controlled for in future studies by standardising the technique used. A small group of participants (16%) were aware of SALAD so the results may not truly reflect the impact of introducing SALAD into a naïve population. No participants suctioned the endotracheal tube prior to SALAD training whereas 97% suctioned the tube following training so the overall times need to take this into account. Conclusions about the SALAD technique need to acknowledge the introduction of the DuCanto catheter for the post-training attempts.

## Conclusion

Teaching NEAS paramedics the SALAD technique resulted in an improvement in intubation success rates without increasing the time taken to intubate. SALAD is a simple technique that can be taught in a short session with simple modifications to equipment commonly used in airway training so would make a valuable addition to paramedic airway training.

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## Competing interests

The authors report no competing interests. Each author of this paper has completed the ICMJE conflict of interest statement.

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## Data availability

The data from this study is available on reasonable request to the authors.

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