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Title:

The reality of advanced airway management during out of hospital cardiac arrest; why did paramedics deviate from their allocated airway management strategy during the AIRWAYS-2 randomised trial?

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Abstract:

Background

AIRWAYS-2 was a large multi-centre cluster randomised controlled trial investigating the effect on functional outcome of a supraglottic airway device (i-gel) versus tracheal intubation as the initial advanced airway management strategy during out-of-hospital cardiac arrest. The AIRWAYS-2 study team collected data concerning deviations from the allocated airway management strategy. We aimed to understand why paramedics deviated from their allocated airway management algorithm during AIRWAYS-2, to gain insights into paramedic decision-making and airway management during out-of-hospital cardiac arrest.

Methods

This study employed a pragmatic sequential explanatory design utilising retrospective study data collected during the AIRWAYS-2 trial. Routinely collected airway algorithm deviation data were analysed to categorise and quantify the reasons why paramedics did not follow their allocated strategy of airway management during AIRWAYS-2. Recorded free text entries collected from AIRWAYS-2 study paramedics by the research team provided additional context to the paramedic decision-making related to each category identified.

Results

In 680 (11.7%) of 5800 patients where advanced airway management was attempted, and the patient was not handed over to another clinician, the study paramedic did not follow their allocated airway management algorithm. There was a higher proportion of deviations in the tracheal intubation group (399/2707; 14.7%) compared to the i-gel group (281/3088; 9.1%). The predominant reason for a paramedic not following their allocated airway management strategy was airway obstruction, occurring more commonly in the i-gel group (109/281; 38.7%) versus (50/399; 12.5%) in the tracheal intubation group.

Conclusion

Airway management during out-of-hospital cardiac arrest is challenging, requiring swift and effective decision-making. During the AIRWAYS-2 trial the most frequent reason for deviating from the airway management algorithm was fluid in the airway, and this occurred most frequently in the i-gel group. Paramedics make pragmatic and best interest decisions regarding airway management during out of hospital cardiac arrest.

Background:

Out-of-hospital cardiac arrest (OHCA) is a unique medical emergency due to the unpredictable and time sensitive nature of the event[1]. Patient survival is in part, dependent on early recognition of OHCA by Emergency Medical Service (EMS) clinicians, the delivery of high quality cardiopulmonary resuscitation (CPR) and the appropriate use of a defibrillator[2]. This is followed by more advanced skills including advanced airway management where indicated. Decision-making must be swift and effective, as represented in the 'chain of survival' model of evidence based OHCA management[3], and be undertaken concurrent with managing an unpredictable environment[4].

AIRWAYS-2 was a large multi-centre cluster randomised controlled trial investigating the effect on functional outcome of a supraglottic airway device (i-gel) versus tracheal intubation (TI) as the initial advanced airway management strategy during OHCA. AIRWAYS-2 included patients who were aged 18 years or older, who had suffered a non-traumatic OHCA and who were treated by an AIRWAYS-2 study paramedic. The trial took place in four EMS providers (NHS ambulance services in England) between June 2015 and August 2017. The design of AIRWAYS-2, the clinical outcomes and relative cost effectiveness of the two strategies, along with the experiences of Emergency Medical Services staff (paramedics) taking part, have been published previously [5–9].

In the AIRWAYS-2 Study, paramedics were instructed to follow an airway management algorithm that required them to make two attempts at placing the randomly allocated airway device (Figure 1). If both these attempts proved unsuccessful then the paramedic could proceed to two attempts at placing the alternative device. If these two attempts were also unsuccessful, further management was at the paramedic's clinical discretion.

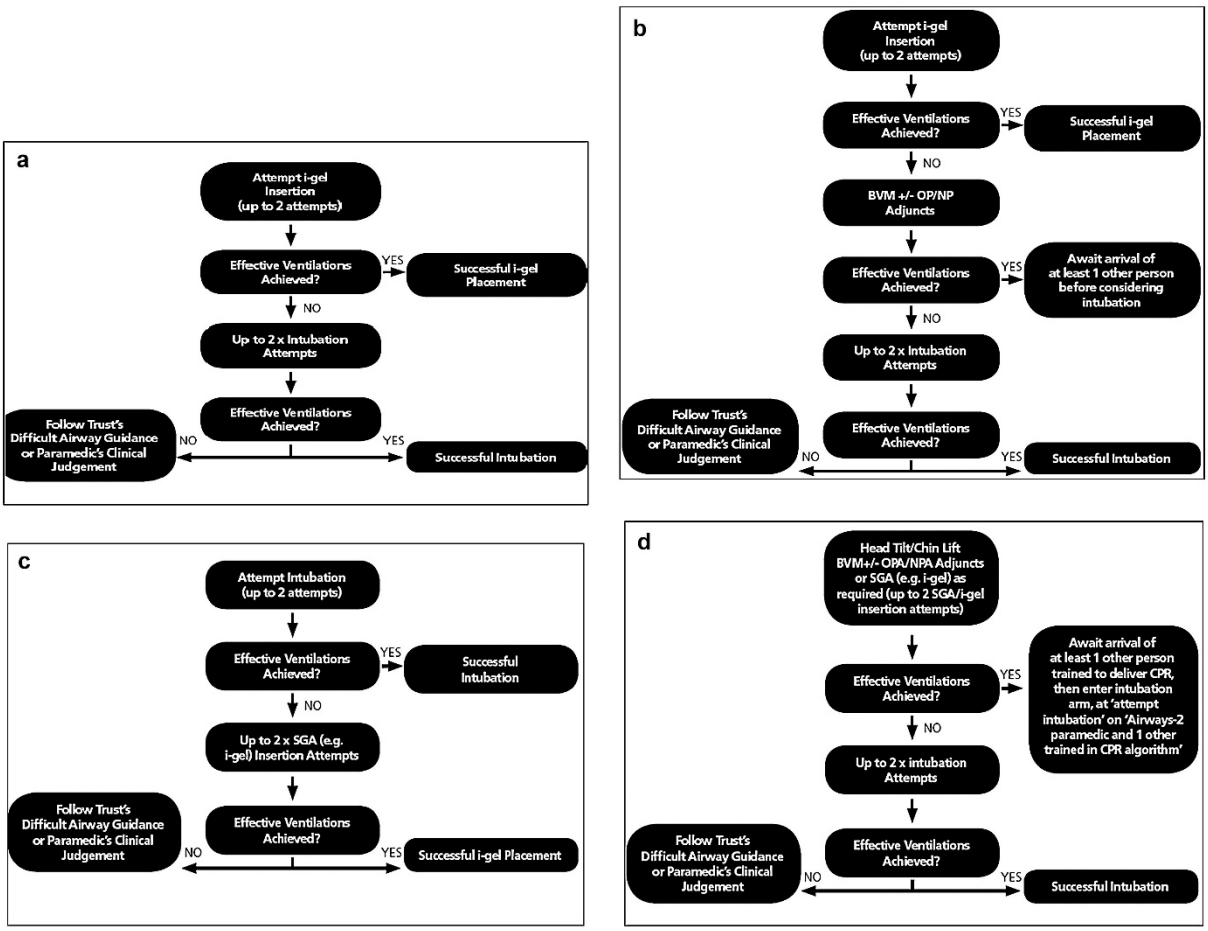

Figure 1: AIRWAYS-2 initial airway management algorithms (a) i-gel Airways-2 paramedic and at least one other person trained in CPR. (b) i-gel Solo Airways-2 Paramedic Response. (c) Intubation Airways-2 paramedic and at least one other person trained in CPR. (d) Intubation Solo Airways-2 Paramedic Response[5]. (Permission to reproduce)

Previously published literature has highlighted the challenges encountered when performing advanced airway management in out-of-hospital care. Including: the negative impact of an unfavourable laryngoscopic view[10]; bodily fluids obstructing the view of the larynx[10,11]; patient obesity[10]; patient positioning[10]; traumatic injuries to the spine or face[10,11] and; limited access to the patient's airway[11].

We anticipated that these challenges would lead to paramedics occasionally deviating from their allocated airway management strategy, and study training emphasised that the clinical needs of each patient were paramount. Therefore, paramedics were empowered to deviate from the trial airway management algorithm if they deemed it to be clinically necessary. Throughout the AIRWAYS-2 trial the research team collected data from study paramedics concerning any deviations that occurred and the reasons for these. Data were entered electronically into a trial database.

The aim of this study was to understand why paramedics deviated from their allocated airway management algorithm during the AIRWAYS-2 randomised trial, and to gain insights into paramedic decision-making and airway management during OHCA. This work has the potential to inform future clinical guidelines, training and research.

Methods:

We used a pragmatic sequential explanatory design utilising retrospective study data. Four English EMS NHS providers participated in AIRWAYS-2[6]. Airway algorithm deviation data collected routinely during the AIRWAYS-2 trial were analysed in order to categorise and quantify the reasons why paramedics did not follow their allocated strategy of advanced airway management (AAM) during the trial. Data were included in the analysis if patients had received at least one attempt at AAM during the trial. An AAM attempt included where a study paramedic used an i-gel or a cuffed tracheal tube in an effort to manage the patient's airway. In 2307/9248 (25%) of patients included in AIRWAYS-2, airway management was handed over to another clinician. Patients where airway management was handed over to another clinician were excluded in order to focus analysis on the decision making of study paramedics.

Reasons for deviating from the AAM strategy were grouped into categories by two researchers, ML and KK. Categories were then quantified according to the study paramedic's allocated airway management strategy. During AIRWAYS-2, reasons why study paramedics deviated from their allocated airway management were recorded as part of the study process. Free text entries collected from AIRWAYS-2 study paramedics by the research team provided additional context to paramedic decision-making in relation to each of the categories identified. One researcher (KK) reviewed the qualitative data and selected data that was representative and added context and explanation to the quantitative data. The four EMS providers that participated in AIRWAYS-2 are represented by the letters A-D

The sponsor for AIRWAYS-2 was South Western Ambulance Service NHS Foundation Trust. Research ethics approval was granted by the Oxford C-South Central Research Ethics Committee (reference 14/SC/1219) and Confidentiality Advisory Group approved the trial under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002. Trial Registration ISRCTN: 08256118.

Results:

During AIRWAYS-2, 9296 patients were enrolled. Of these, 4410 patients were allocated to tracheal intubation (TI) and 4886 to the supraglottic airway device (i-gel). In total, there were 5800 patients where AAM was attempted, and the patient was not handed over to another clinician. Table 1 indicates that of these 5800 patients, the study paramedic did not follow their allocated airway management algorithm in 680 (11.7%) patients. There was a higher proportion of deviations in the TI group (399/2707; 14.7%) compared to the i-gel group (281/3088; 9.1%).

Table 1: Proportion of patients where the allocated airway algorithm was not followed in eligible patients where advanced airway management was attempted, and the care of the patient was not handed over to another clinician

	Randomised to TI (n=2708)	**Randomised to i-gel (n=3092)**	**Overall (n=5800)**
Did not follow allocated algorithm where AAM was attempted and patient care was not handed over	399/2707 (14.7%)	281/3088 (9.1%)	680/5795 (11.7%)
Missing "algorithm followed" data	1/2708 (0%)	4/3092 (0.1%)	5/5800 (0.1%)

Table 2 categorises the reasons why paramedics did not follow their allocated airway management algorithm, and the number of patients in the TI and i-gel groups where this occurred. Table 3 reports the primary outcome of the main AIRWAYS-2 trial for those who followed and did not follow the allocated airway management algorithm.

Table 2: Reasons why paramedics did not follow their allocated airway management algorithm in the TI and i-gel groups

	Randomised to TI (n=399)		**Randomised to i-gel (n=281)**		**Overall (n=680)**	
Reasons for not following algorithm						
Obstruction/blood/fluid in airway	50/399	12.5%	109/281	38.7%	159/680	23.4%
Clinical decision	71/399	17.8%	50/281	17.8%	121/680	17.8%
No reason given	44/399	11.0%	38/281	13.5%	82/680	12.1%
Space/position issues	65/399	16.3%	0/281	0%	65/680	9.6%
Did not have equipment/equipment problem/equipment failure	23/399	5.8%	31/281	11.0%	54/680	7.9%
Forgot to enrol	33/399	8.3%	23/281	8.2%	56/680	8.2%
Patient's anatomy	33/399	8.3%	11/281	3.9%	44/680	6.5%
Solo responder	23/399	5.8%	1/281	0.4%	24/680	3.5%
Futility	16/399	4.0%	4/281	1.4%	20/680	2.9%
ROSC/good respiratory effort	15/399	3.8%	7/281	2.5%	22/680	3.2%
Poor view	20/399	5.0%	0/281	0%	20/680	2.9%
DNAR	4/399	1.0%	1/281	0.4%	5/680	0.7%
No ETCO2 monitoring	0/399	0%	4/281	1.4%	4/680	0.6%
Other	0/399	0.5%	1/281	0.4%	1/680	0.2%

ROSC: return of spontaneous circulation; DNAR: do not attempt resuscitation; ETCO2: end-tidal carbon dioxide.

Table 3: Primary trial outcome for patients receiving at least one AAM attempt and who were not handed over to another clinician according to whether they followed the allocated airway management algorithm, by treatment group and overall

	Randomised to TI (n=399)		**Randomised to i-gel (n=281)**		**Overall (n=680)**	
Primary Outcome:						
Did not follow the allocated algorithm						
Good functional recovery (mRS 0-3 at 30 days/hospital discharge)	11/399	2.8%	6/281	2.1%	17/680	2.5%
Followed allocated algorithm						
Good functional recovery (mRS 0-3 at 30 days/hospital discharge)	44/2308	1.9%	97/2807	3.5%	141/5115	2.8%

mRS: modified Rankin Scale.

Obstruction/blood/fluid in airway

The most frequent reason for deviating from the allocated airway algorithm was recorded as an airway obstruction which included blood and fluid in the airway. Deviating for this reason occurred in both groups of the trial, but occurred more frequently in the i-gel group (12.5% TI; 38.8% i-gel). Free text data indicated that there is a preference for TI over i-gel when a patient's airway is compromised by fluid, with a suggestion that the i-gel can become impractical when used in a patient with an airway that contains fluid.

Quote One: *"Clinical decision to intubate due to amount of fluid in airway" (C5734)*

Quote Two: *"i-gel first despite being on intubation group and part of a crew. 1. There was initially a lot of regurgitation, an OP[oropharyngeal airway] was ineffective and I attempted to ventilate with an i-gel whilst the intubation equipment was prepared. The patient was then successfully intubated. 2. The tube seemed to become displaced and on an attempt to re-intubate the laryngoscope blade failed to light up, so an i-gel was used again whilst a replacement was sourced. Once sourced the next attempt was successful" (A19548)*

Quote Three: *"Only 1 attempt at i-gel I think it was properly sited but was spraying vomit across the trolly & clogging up so there didn't see any point in reinserting it" (A18408)*

Clinical decision

The "clinical decision" category included a number of reasons for paramedics deviating from their allocated algorithm and occurred equally between groups (TI 17.8%; i-gel 17.8%). Decisions were made to support the patient's best interests for the situation at the time.

Quote Four: *"After an intubation attempt swapped to OPA [an oropharyngeal airway] rather than another attempt with advanced equipment. Neither ETT/I-gel had worked well; thought best for patient" (A2763)*

Quote Six: *"Difficult scene to manage, clinical decision to use i-gel" (B8908)*

Space/position issues

The category of space/position issues was limited to the TI group where 16.3% of deviations from the allocated algorithm were for this reason. Interestingly, 100% of these patients had died by 30 days or hospital discharge.

Quote Seven: *"i-gel was used first as space was very tight on site" (A1832)*

Quote Eight: *"Space position issues. Cardiac arrest on train. Used LMA [laryngeal mask airway]" (D9258)*

Did not have equipment/equipment problem/equipment failure

Algorithm deviations in this category occurred more frequently in the i-gel group than the TI group (TI 6.0%; i-gel 11.0%). One EMS provider (Service D) did not have i-gels as standard issue and paramedics in this service were allocated trial i-gels that the paramedic had to remember to take to an OHCA. This accounted for 29/31 (93.5%) of the deviations from the algorithm for this category in the i-gel group. Paramedics in the TI group also reported not expecting an OHCA on arrival at the patient, and so did not have the correct equipment on hand to perform TI. In addition there were occasional equipment failures reported as illustrated in Quote 10.

Quote Nine: *"Job not passed as cardiac arrest, therefore i-gels not with paramedic" (D2283)*

Quote Ten: *"Failure of laryngoscope light meant swapped method" (A1178)*

Patient anatomy

Deviating because of the patient's anatomy was more prominent in the TI group than the i-gel group (TI 8.3%, i-gel 3.9%)

Quote Eleven: *"Abnormal patient anatomy unable to ETT [endotracheal tube]/igel" B13969*

Quote Twelve: *"One intubation attempt. Grade 4 view, very big neck, stuck to basics" (D591)*

Solo Responder

Paramedics randomised to the intubation group who found themselves being a lone responder in attendance at an OHCA, were permitted to use an i-gel as their initial airway management attempt. This pragmatic approach was adopted because a lone clinician cannot intubate a patient and maintain effective cardiopulmonary resuscitation (CPR) and at least one other person must be in

attendance to facilitate this. This explains why this deviation from the algorithm occurred predominantly in the intubation group.

Quote Thirteen: *"Had 3 attempts with i-gel before switching method. This was due to solo responder for long time, attempted 2 x size 4, while waiting wanted to go to size 5 i-gel just to check it wasn't poor selection" A04108*

Quote Fourteen: *"Unable to intubate due to being a solo responder and crew 20 minutes away" (D391)*

Futility

Paramedics occasionally deviated from the allocated algorithm where it became apparent that continued resuscitation would be futile.

Quote Fifteen: *"Intubation group of trial but only one i gel attempt. AIRWAYS-2 study paramedic believed situation futile" (A6243)*

ROSC/good respiratory effort

Patients were enrolled in the AIRWAYS-2 trial where they suffered a non-traumatic OHCA. In a proportion of the patients enrolled, prompt treatment such as early defibrillation was successful and resulted in a return of spontaneous circulation (ROSC) impacting on the success and choice of AAM. Deviations from the allocated algorithm, where the patient had a ROSC or was making good respiratory effort occurred more frequently in the TI group of the trial (TI 3.8%, i-gel 2.5%). This is likely to reflect the fact that it takes longer to prepare for TI than i-gel. As a result of this time delay in attempting AAM in the TI group, the patient was more likely to achieve a ROSC and become less tolerant of AAM. Unsurprisingly, 31.8% of this group of patients survived with a good functional outcome.

Quote Sixteen: *"Making resp[iratory] effort on arrival, unable to tube" (B16471)*

Quote Seventeen: *"ROSC before 2nd igel attempt"* (D14991)

Poor view

This deviation was limited to the TI group of the trial and was documented where the study paramedic did not obtain an adequate view of the vocal cords during laryngoscopy. None of these patients survived the event with a good functional outcome.

Quote Eighteen: *"Unable to visualise cords and confirm correct placement. Then patient had trismus" (B118)*

Do Not Attempt Resuscitation Order

A small number of deviations occurred where paramedics became aware of a Do Not Attempt Resuscitation order.

Quote Nineteen: *"DNAR in place ? valid. Once details confirmed resus stopped" (B16702)*

Discussion

The results of this analysis of airway management algorithm deviation during the AIRWAYS-2 trial provide valuable insights into paramedic decision-making when providing advanced airway management during an out-of-hospital cardiac arrest. The reasons recorded for paramedics deviating from the prescribed airway management algorithm included: airway obstruction, clinical decision, space and position problems, equipment issues, the patient's anatomy, solo responding, futile resuscitation, ROSC or respiratory effort, poor view and presence of a DNAR order.

The most frequent reason recorded for a deviation was an obstruction of blood or fluid in the patient's airway, with this occurring more frequently in the i-gel group. Emesis has been reported in 32% of OHCAs and is associated with reduced survival[12]. A soiled airway presents challenges unique to this setting. A case series[13] of aspiration during in-hospital anaesthesia reported one case of the i-gel failing to protect the airway from aspiration. In the same case series, another two patients regurgitated and their airway was protected by the i-gel. The i-gel has been found previously to be less effective at preventing aspiration than a device with an inflatable cuff, and supraglottic airway devices are recognised as being less effective at preventing aspiration than TI[14]. Previous research by Voss and colleagues [15] recognised that paramedics commonly change their airway choice because of regurgitation, however the authors could not determine whether regurgitation made ventilation impossible, or whether the paramedic was concerned about the risk of aspiration. This present study finds that paramedics make this decision based on the perceived risk of aspiration as well as failure to ventilate the patient.

Conversely, paramedics also made decisions to use the i-gel rather than TI when the patient's airway was obstructed by fluid. A recent study investigating drug assisted intubation by anaesthetists using video laryngoscopy found that 77% of failed first pass attempts were due to an airway obstructed by vomit, food, mucus or blood[16]. A soiled airway remains very challenging for paramedics to manage effectively in the out-of-hospital environment.

A "clinical decision" for deviating from the allocated algorithm incorporated a number of different scenarios where the paramedic adapted their management to the situation. This category reflects the challenging and dynamic nature of OHCA. Other reasons for deviating from the allocated algorithm were specific to the advanced airway, for example requiring space to perform tracheal intubation, space for an assistant and space for the equipment. In contrast, i-gel placement is generally easier than TI, and can be completed by a single operator with a median insertion time of 11 seconds in one study[17]. Conversely TI has been indicated to take a median time of five minutes during in-hospital cardiac arrest[18], and this time would be expected to be longer out-of-hospital. Having a "poor view" was also limited to TI deviations because successful intubation requires direct visualisation of the vocal cords and passage of the tracheal tube[1920]. Deviation due to the patient's anatomy was linked closely to "poor view." There are known anatomical predictors for a difficult intubation including obesity, short neck, limited neck extension and large neck circumference[21]. TI cannot be performed by a solo responder without interrupting lifesaving CPR whilst intubation is taking place; therefore this deviation was permitted in the algorithm during AIRWAYS-2 and reflected in Figure One.

The strength of this study is that it explores the airway management decisions of paramedics taking part in a large multi-centre prospective trial of advanced airway management in out-of-hospital cardiac arrest. Limitations include reliance on study paramedic self-report regarding the reasons that they deviated from their allocated airway management strategy. No statistical tests were planned or completed. In addition, this study was limited to EMS providers in England and may not be generalisable to international EMS systems. This research provides detailed context regarding the airway management decisions that EMS clinicians (paramedics) make in practice.

Following the publication of the primary results from AIRWAYS-2, tracheal intubation was de-emphasised in the 2021 Resuscitation Guidelines, [22] and it was suggested that only rescuers with a high TI success rate should perform TI. In many UK EMS services intubation is now an enhanced skill and not standard paramedic practice. Removing intubation from standard paramedic practice potentially creates challenges if a supraglottic airway device such as the i-gel does not protect a patient's airway from aspiration or allow adequate ventilation and clinical staff with enhanced skills are not immediately available to support.

Further research could usefully investigate how paramedics should optimise their management of the patient when the airway is soiled. There is potential to include enhanced advice for callers to EMS via Emergency Medical Dispatchers when the airway has become obstructed prior to EMS arrival. Further research could also seek to understand the reasons why patients in the TI group of the trial did worse than patients in the i-gel group of the trial in terms of functional recovery where the allocated airway algorithm was adhered to. However, this would be more challenging to complete now that TI has been de-emphasised from standard paramedic practice. We also recommend enhanced training for paramedics in the use of supraglottic airway devices, and particularly the management of a soiled airway.

Conclusion

This study highlights the challenges that paramedics face when managing a patient's airway during OHCA. AIRWAYS-2 study paramedics did not follow their allocated airway management algorithm in 680 (11.7%) of 5800 patients. There was a higher proportion of deviations in the TI group (399; 14.7%) compared to the i-gel group (281; 9.1%). The most frequent reason for deviating from the allocated airway management algorithm in AIRWAYS-2 was obstruction of the patient's airway by fluid. This occurred in both groups of the AIRWAYS-2 trial, but was more frequent in the i-gel group. Paramedics make pragmatic and best interest decisions for patients in this unpredictable and dynamic situation.

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