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Effect of intermediate airway management on ventilation parameters in simulated paediatric out-of-hospital cardiac arrest: a multicentre randomised crossover trial

Loric Stuby[a], Laurent Bourgeois[b], Jean-Marie Tinembart[c], Elisa Mühlemann[bc], David Thurre[d], Johan N. Siebert[e], Laurent Suppan[f]

[a] Genève TEAM Ambulances, Emergency Medical Services, Geneva, Switzerland
[b] ESAMB – College of Higher Education in Ambulance Care, Conches, Switzerland
[c] Service de la Protection et de la Sécurité, Emergency Medical Services, Neuchâtel, Switzerland
[d] Martigny Region, Fire Rescue Centre, Martigny, Switzerland
[e] Division of Paediatric Emergency Medicine, Geneva Children's Hospital, Geneva University Hospitals, Geneva, Switzerland
[f] Division of Emergency Medicine, Department of Anaesthesiology, Clinical Pharmacology, Intensive Care and Emergency Medicine, Geneva University Hospitals, Geneva, Switzerland

Summary

INTRODUCTION: Paediatric out-of-hospital cardiac arrest survival rates remain low despite advancements in resuscitation science. Prompt restoration of oxygenation is crucial for achieving return of spontaneous circulation. Delays in airway management are associated with decreased survival rates. The primary objective of this study was to determine whether early i-gel® insertion, without prior bag-valve-mask, could enhance ventilation parameters in comparison with a bag-valve-mask-only approach.

METHODS: This multicentre, randomised crossover study used a simulated paediatric out-of-hospital cardiac arrest model to compare standard American Heart Association guidelines with an intermediate airway management approach using an i-gel® device. Paramedics and emergency medical technicians from eight participating emergency medical service centres were randomised into teams and performed two 10-minute simulations. Each team employed one of the airway management strategies. Data was automatically collected by a high-fidelity manikin. The primary outcome was alveolar ventilation per minute. Secondary outcomes included metrics for ventilation quality and timing, chest compression performance and timing of adrenaline administration. Statistical analysis involved paired tests suitable for the crossover design.

RESULTS: From 30 January 2023 to 13 June 2023, 68 participants formed 34 resuscitation teams. Minute alveolar ventilation was similar between intermediate airway management and bag-valve-mask strategies (difference: 36 ml [95% CI −28 to 99]). A sensitivity analysis showed comparable results. Intermediate airway management delivered more ventilations, but bag-valve-mask enabled quicker ventilation initiation and more ventilations within the target volume. Chest compression fraction was higher with intermediate airway management, although chest recoil was better with bag-valve-mask. Adrenaline administration rates and times were similar in both strategies. Minor protocol deviations were observed but did not introduce significant bias. The study was underpowered due to an error in the sample size calculation, limiting the robustness and generalisability of the findings.

CONCLUSION: In a simulated paediatric out-of-hospital cardiac arrest model, immediate use of intermediate airway management did not show relevant differences compared to bag-valve-mask. Intermediate airway management devices cannot be recommended as first-line choice but may be considered when bag-valve-mask is challenging. Whichever device is used, the focus should remain on providing high-quality ventilations.

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Loric Stuby
Genève TEAM Ambulances
Emergency Medical Services
CH-1201 Geneva
l.stuby[at]gt-ambulances.ch

Introduction

Background

Despite significant advancements in resuscitation science, paediatric out-of-hospital cardiac arrest survival rates remain low (0.0% to 21.2%) [1–3]. These unsatisfactory rates, combined with the particularly high incidence of paediatric out-of-hospital cardiac arrest in infants less than a year old (20.9 to 23.42 per 100,000) [4, 5], underscore the need for continued efforts to mitigate risk factors and optimise survival. Causes of paediatric out-of-hospital cardiac arrest include hypoxia, heart diseases, trauma and sudden infant death syndrome, among others [4–8]. In older children, the incidence of paediatric out-of-hospital cardiac arrest is 3.7 per 100,000, with mostly noncardiac aetiologies (particularly respiratory events), leading to non-shockable rhythms [9]. Prompt restoration of oxygenation is crucial for achieving return of spontaneous circulation. Delays in airway management are associated with de-

creased survival rates [10]. However, there is limited data on the effects of different paediatric airway management strategies in paediatric out-of-hospital cardiac arrest [11, 12]. Simple and straightforward airway management procedures are often advocated since young age is associated with higher rates of adverse events when advanced airway management procedures are used in prehospital paediatric out-of-hospital cardiac arrest [13].

Emergency medical services typically use bag-valve-mask devices for oxygenation in these cases [14]. However, bag-valve-mask devices have several clinically significant limitations, including leakage and gastric insufflation [15–20], and negatively impact venous return [19, 21, 22]. Additionally, using bag-valve-mask devices requires interruption of chest compressions, which decreases blood flow and is associated with lower survival rates [20]. Advanced airway management procedures such as endotracheal intubation offer optimal airtightness but require advanced skills and may introduce delays [23–28].

Intermediate airway management using supraglottic airway devices such as the i-gel® could be a promising alternative. In adult patients, in addition to ease of insertion and high success rates [29–38], intermediate airway management allows for continuous chest compressions and generates improved ventilation parameters [39–43]. Compared to endotracheal intubation, intermediate airway management leads to faster airway placement and potentially more return of spontaneous circulation, though the impact on long-term survival and aspiration events remains uncertain [44]. Emerging evidence supports the use of intermediate airway management devices in paediatric patients, with higher success rates and similar outcomes compared to endotracheal intubation [45–48].

However, data on the impact of intermediate airway management on ventilation parameters during paediatric out-of-hospital cardiac arrest remains limited, as most studies, primarily registry-based, have focused on advanced airway management, including both supraglottic airways and tracheal intubation, whereas each technique should be evaluated separately. Therefore, the need to specifically assess intermediate airway management as a distinct category has been previously emphasised [49]. Our study hypothesis was that early insertion of an i-gel® device without prior bag-valve-mask ventilation may enhance ventilation parameters compared to the standard bag-valve-mask-only approach.

Objectives

The primary objective of this study was to determine whether an intermediate airway management strategy, consisting of immediate i-gel® insertion followed by asynchronous ventilations, improved the minute alveolar ventilation in a simulated model of paediatric out-of-hospital cardiac arrest, compared to the standard approach according to the American Heart Association (AHA) guidelines [14].

The secondary objective was to compare the impact of these approaches on metrics for ventilation quality and timing, as well as chest compression quality (rate, depth, chest recoil and chest compression fraction), and on the ability to rapidly administer intravenous adrenaline.

Materials and methods

Study design and setting

This was a multicentre, superiority, randomised crossover study based on a simulated model of paediatric out-of-hospital cardiac arrest. The study protocol has been published [50]. This manuscript complies with the extension for randomised crossover trials of the Consolidated Standards of Reporting Trials guidelines [51]. The trial was carried out according to the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. A waiver of consent was obtained from the local ethics committee (CCER – Req-2022-00859].

In Switzerland, the organisation of prehospital emergency medical services (EMS) varies considerably from canton to canton. Ambulances are mainly staffed by paramedics, who have completed a three-year curriculum and represent the highest level of non-medical prehospital care [52]. In several cantons, paramedics team up with emergency medical technicians (EMT), who are certified after one year of training. Depending on the cantonal organisation, nurses may be present in ambulances instead of EMTs or paramedics. In most cantons, when a life-threatening emergency is identified by dispatchers, medical reinforcement is provided by a light vehicle, the *Service Mobile d'Urgence et de Réanimation,* staffed by an emergency physician and a paramedic or specialised nurse. Emergency medical service helicopters, each staffed by a paramedic, an emergency physician and a pilot, are also available and dispatched according to specific criteria. Medical reinforcement can be sent simultaneously with the ambulance or requested by the paramedics after arriving at the scene. In certain regions, a paediatrician may be dispatched to manage specific paediatric cases.

Among the study centres, four were based in the Canton of Geneva (Genève TEAM Ambulances, SK Ambulances, ACE Genève Ambulances, SAG Secours Ambulances Genève), one in the Canton of Valais (Centre de Secours et d'Urgence de la Ville de Sion) and three in the Canton of Neuchâtel (Ambulances des Vallées Neuchâteloises, Service d'Incendie et de Secours [SIS] des Montagnes Neuchâteloises, Service de la protection et de la sécurité [SPS] Neuchâtel).

Participants, inclusion and exclusion criteria

Paramedics and EMTs currently employed at any of the participating study centres were eligible for inclusion. All these centres use i-gel® devices as part of their standard clinical procedures. The sole exclusion criterion was being a member of the study team. A local study coordinator recruited the participants using a standardised email template that provided comprehensive information about the study, including data protection policies. Participants were blinded to specific study outcomes to prevent preparation bias, even though they were informed that the study was about out-of-hospital cardiac arrest management. Participation was voluntary, and participants were free to withdraw at any time without providing a reason. No incentives were provided. All participants of the study provided written informed consent. Prior to signing the informed consent form, participants were given ample time and oppor-

tunity to ask questions. All participants were presumed to possess comparable skills in bag-valve-mask ventilation and i-gel® use, consistent with their regular practice and training background.

Two-tiered randomisation and allocation concealment

Two levels of randomisation were applied. First, each trial centre served as a cluster, and teams underwent initial intra-cluster randomisation. This process employed an online balanced team generator [53], stratified by professional status to ensure that there was at least one paramedic per team. When mixed teams were created (i.e. with an EMT), the paramedic consistently assumed the role of "team leader". Within paramedic-only teams, participants chose their roles freely, consistent with actual clinical practice. Throughout all scenarios, team leaders retained their positions.

After a self-directed training session supported by two demonstration videos, the second level of randomisation (team level) took place. The videos, each lasting just over a minute, served as a presentation of the approach to be adopted. For the standard approach, the video demonstrated the application of the AHA recommendations [14], which involved alternating cycles of 15 compressions and 2 ventilations, starting with compressions. For the experimental approach, the sequence also began with compressions, followed by the insertion of the i-gel without prior bag-valve-mask ventilation, after which asynchronous ventilations were delivered at a rate of 20–30 per minute (or one ventilation every 2–3 seconds). For both approaches, the videos stressed the importance of alternating roles every 2 minutes. No mention of the placement or use of defibrillation pads was provided in either video.

Teams were then randomly assigned to one of the two study paths by picking up an opaque, sealed envelope created using a block randomisation list (blocks of size 2 and 4) generated online, with a 1:1 ratio [54]. This randomisation was stratified by centre, primarily due to logistical considerations (different sessions) but also to accommodate differences among participants, such as initial airway management strategies, task allocation, local cardiopulmonary resuscitation (CPR) procedures, quality assurance processes or previous specialised training.

The allocation was only disclosed when the team leader opened the sealed envelope just before starting the first simulation, thereby minimising induced biases. Once allocation was known, no further contact between the investigators and the participating teams was allowed.

Study paths

Consistent with previous findings showing no significant difference between the European Resuscitation Council approach and the AHA approach [55], the AHA guidelines were chosen as the standard [14]. Both guidelines recommend alternating 15 compressions and 2 ventilations. The AHA guidelines start with compressions, whereas the ERC guidelines begin with five initial rescue breaths.

The experimental approach, i.e. using intermediate airway management, involved the immediate insertion of an i-gel® device without prior bag-valve-mask ventilation. Continuous chest compressions were to be initiated upon identification of cardiac arrest. Once the i-gel® device was inserted, ventilations were administered asynchronously at a rate of 20–30 per minute, in accordance with AHA recommendations [14].

Following the crossover design, teams applied both approaches in a random order. Half of the teams performed the first paediatric out-of-hospital cardiac arrest simulation using the standard approach, followed by a second simulation using the experimental approach. The other half did the reverse.

Manikin and resuscitation equipment

Throughout the study, the same high-fidelity Wi-Fi manikin and dedicated multiparametric monitor/defibrillator (Laerdal SimBaby, Laerdal Medical, Stavanger, Norway) were used. All study outcomes, including chest compression rate, depth, recoil, ventilation volume and rate, were automatically recorded by the manikin, except for the timing of the adrenaline injection, which was manually tagged. Representing a 9-month-old infant with a height of 71 cm, the SimBaby is marketed as a realistic manikin but actually weighs 4.9 kg. To maintain consistency with age, the simulated infant's weight was communicated to participants to be 9 kg based on the appropriate Best Guess formula: (0.5 × age in months) + 4.5 [56].

Teams were allowed to use their full resuscitation equipment, such as oropharyngeal cannulas, allowing them the flexibility to choose their preferred tools during the simulation. The decision regarding the use of any specific item remained solely at the discretion of the team members, mirroring real-life resuscitation scenarios. A back compensation, using a folded blanket, was already set up. Only appropriately-sized airway management devices (bag-valve-mask device and i-gel®, size 1.5 Intersurgical Ltd, Wokingham, UK) were available.

Paediatric cardiac arrest scenario

The scenario was standardised and precisely detailed in the study protocol [50]. Participating teams engaged in two consecutive, identical 10-minute realistic paediatric out-of-hospital cardiac arrest scenarios. The start (T0) was defined as the first compression or the first ventilation, whichever occurred first. To enhance fidelity, two stressors were used: a simulated parent, portrayed by the same female investigator, whose role was to enquire about the situation at scripted intervals, and simulated traffic noises. The scenario began with a clinical statement acknowledging the life-threatening condition of the patient, followed by the team leader restating for confirmation. The simulated child was apnoeic and pulseless, displaying asystole upon electrode placement. CPR waves were automatically displayed during compressions, with subsequent rhythm analyses consistently showing refractory asystole. An intravenous/intraosseous access could be obtained successfully on the first attempt. After the first simulation, the equipment was restored. Then, the exact same scenario was repeated with the alternative airway management strategy, without additional interaction with the study team.

Outcomes

The primary outcome was the minute alveolar ventilation, calculated by subtracting the dead space volume from each ventilation, multiplying by the number of ventilations, and dividing by the time elapsed.

The secondary outcomes were:

- The proportion and number of ventilations below (<45 ml), within (45–72 ml) and over (>72 ml) the target volume;
- Time to the first efficient ventilation (measured as the time elapsed from T0 to the first ventilation with a volume of ≥45 ml);
- Time to first compression (measured as the time elapsed from T0 to the first compression);
- Chest compression fraction (cumulative time spent providing chest compressions over the total time of resuscitation);
- Chest compression rate (compressions per minute, cpm);
- Proportion of chest compressions below (<100/minute), within (100–120/minute) and over (>120/minute) the target rate;
- Chest compression depth;
- Proportion of chest compressions below (<4.3 cm) and within (≥4.3 cm) the target depth (this threshold corresponds to one third of the manikin's measured antero-posterior chest depth);
- Proportion of complete chest recoil;
- Time to first adrenaline injection (measured as the time elapsed from T0 to the first injection);
- Proportion of scenarios in which adrenaline was administered within 5 minutes.

Although not included in the protocol, it was decided before data collection to also assess overall ventilation volume and the total number of ventilations.

Sample size calculation

The protocol's sample size calculation was incorrect in estimating the number of ventilations with the bag-valve-mask. The protocol anticipated ventilations being provided for only 8 minutes (given the time necessary to prepare ventilation devices). In an adult scenario lasting 10 minutes, there were 39 ventilations in the intermediate airway management approach (with a target rate of 10/minute) and 19 in the bag-valve-mask approach (ratio of 2 ventilations per 30 compressions) [41]. In this study, targeting a ventilation rate of 20–30/minute, around 100 ventilations were expected with the intermediate airway management approach, while the protocol erroneously expected 40 ventilations with the bag-valve-mask approach. The correct expectation should have been around 80 ventilations, given that a ratio of 2 ventilations per 15 compressions yields 10 ventilations/minute, totaling 80 ventilations over 8 minutes. The tidal volume was estimated to be similar with both devices [55], approximately 52 ml, equating to 25 ml of alveolar ventilation. The expected difference in alveolar minute ventilation between bag-valve-mask and intermediate airway management devices was planned to be 185 ml (125 ml versus 310 ml). Data variability was estimated with a standard deviation of 140 ml. A correlation of 0 was used in the calculation to ensure a larger and more cautious sample size, though this assumption disregards the expected positive correlation in a crossover design. With a Type 1 error set at 5% and a power of 90%, the erroneous requirement was 15 teams (30 simulations). However, with the corrected expectation of 80 ventilations (alveolar minute ventilation of 250 ml, with a difference of 60 ml), the actual required sample size should be 117 teams. Consequently, this study is underpowered, with an intraclass correlation coefficient of 0.0065 and a post hoc power estimate of 16.7%.

Blinding, bias minimisation, data collection and extraction

Data was automatically collected by the manikin's sensors and exported to a CSV file to prevent assessment bias. A custom PHP script generated variables of interest [57]. Demographics were collected directly through a web-based platform to which participants logged in using the coded identifier of their team, which was written on the outside of the sealed envelope. The curated databases were sent in DTA format to the blinded data analyst. All investigators had access to the data file.

Statistical analysis

The statistical analysis plan was described in the published protocol [50]. Data distribution was assessed graphically and using the Shapiro-Wilk test in case of doubt. Variables were described accordingly using either median [Q1–Q3] or mean (standard deviation [SD] and/or 95% confidence interval [CI]) depending on their distribution. Due to the crossover design, variable dependency was considered by using paired tests (paired Student's t-test or Wilcoxon matched-pairs signed-rank test depending on the assumptions) for continuous variables, and McNemar's test for paired nominal data. Analysis was performed on an intention-to-treat basis. A sensitivity analysis, not anticipated in the protocol but decided prior to data collection, was performed by analysing the primary outcome with ventilation capped at 70 ml to ensure a potential difference was not related to hyperventilations. After a first team-based analysis (with means as unity of analysis), a more in-depth analysis was carried out by graphically assessing the ventilation volume at a ventilation-based level (with ventilation as the unit of analysis). All statistical tests were two-sided, with statistical significance set at 5%. Missing data was treated as such. Data analysis was carried out using Stata V15.1 (StataCorp LLC, College Station, TX, USA).

Protocol deviations

There was no major deviation from the planned protocol. However, minor protocol deviations occurred and were noted to ensure transparency and accuracy in reporting the study findings.

1. *Inclusion of nurses*: Two nurses were enrolled in the study, whereas the study protocol only mentioned EMTs and paramedics. However, both nurses were currently only working in the prehospital field and were teamed up with a paramedic who acted as the

team leader. This deviation is not expected to have introduced any significant bias.

2. *Chest compression depth target*: The chest compression depth target had to be modified to yield relevant information. The protocol initially specified a 3 cm cutoff, but the manufacturer's target is 4 to 5 cm [58], and this latter target was ultimately used. This change was made prior to data collection.
3. *Ventilation volume*: Ventilation volume was added as an outcome.

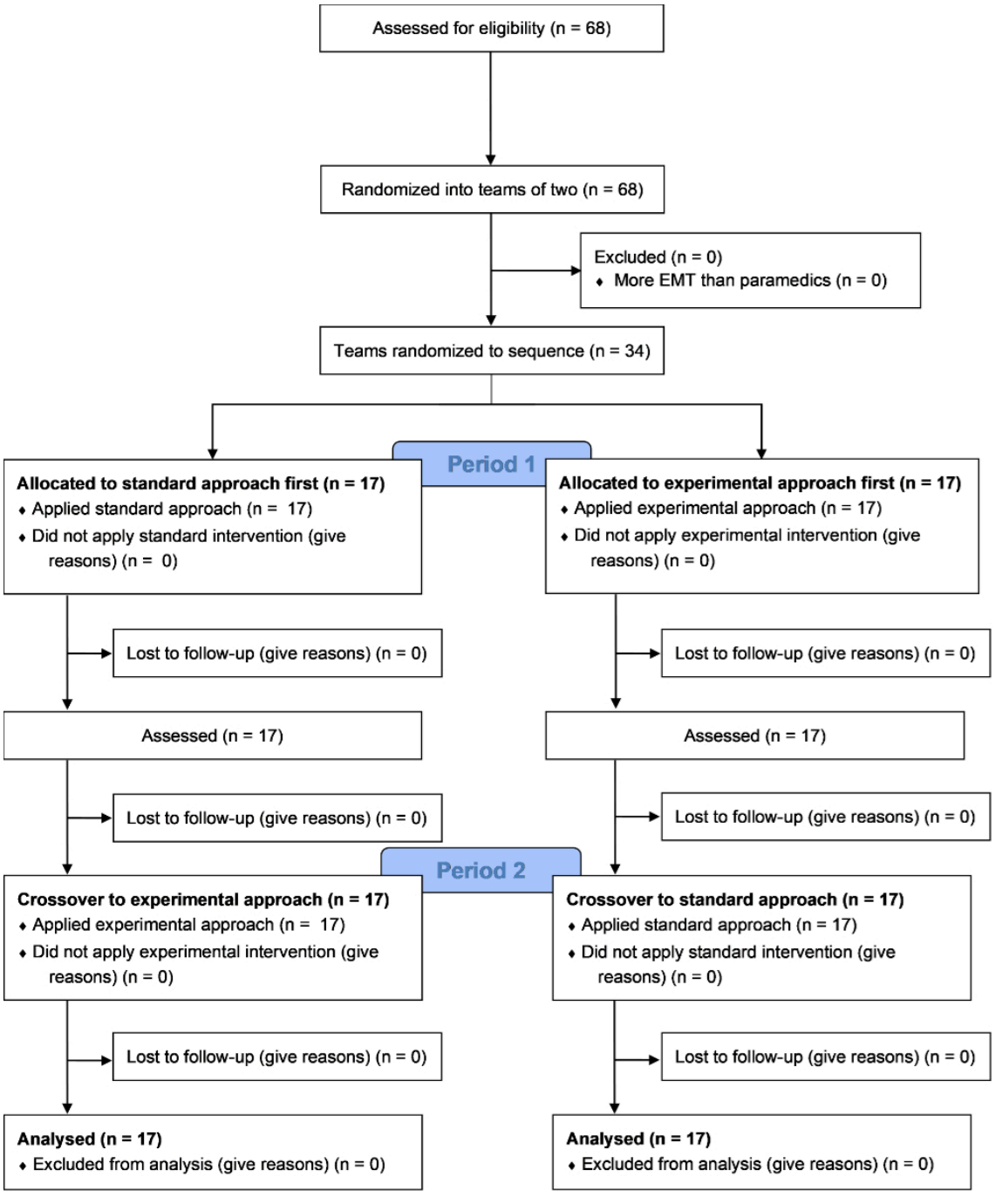
Institutional review board statement

The trial received a declaration of no objection by the Geneva Cantonal Research Ethics Commission on 19/07/2022 (Req-2022-00859). The trial was conducted according to the principles of the Declaration of Helsinki and Good Clinical Practice guidelines.

Results

Sixty-eight participants were recruited from 8 different emergency medical services and distributed into 34 teams (figure 1). Their characteristics are presented in table 1. There were no missing data.

Figure 1: Study flowchart. EMT: emergency medical technicians.



Primary outcome

Minute alveolar ventilation was not significantly different when using the intermediate airway management strategy compared to bag-valve-mask (258 ml [95% CI 190 to 326] versus 222 ml [95% CI 194 to 250]; difference of 36 ml [95% CI −28 to 99]) (figure 2). When capping each ventilation at 70 ml according to the sensitivity analysis, similar results were found (197 ml [95% CI 155 to 238] with intermediate airway management compared to 185 ml [95% CI 164 to 206] with bag-valve-mask; difference of 11 ml [95% CI −29 to 51]).

Ventilation secondary outcomes

More ventilations were delivered when using intermediate airway management, with a consistent mean volume regardless of the airway management strategy. The use of bag-valve-mask enabled quicker initiation of ventilation and provided more ventilations within the target volume (table 2).

Chest compression outcomes

All teams started with chest compressions, resulting in a duration of 0 seconds to the first compression. The chest compression fraction was significantly higher when using intermediate airway management compared to bag-valve-mask. In contrast, chest recoil was better with the bag-valve-mask strategy (table 3). All other compression outcomes were similar.

Other secondary outcomes

The proportion of scenarios in which adrenaline was administered was similar with both strategies (table 4), as was the proportion in which it was administered within 5 minutes (table 5).

The time to the first adrenaline injection was similar with both strategies, with a median [Q1–Q3] time of 420 seconds [365; 494] when using bag-valve-mask versus 420 seconds [359; 490] with intermediate airway management, yielding a difference of 14 seconds [−85; 67].

Detailed post hoc analysis of ventilations

A total of 5944 ventilations was included in the database (table 6).

The variability in ventilation volume was higher when using the intermediate airway management strategy compared to the bag-valve-mask strategy (figure 3).

Discussion

Main considerations

In this study comparing intermediate airway management and bag-valve-mask ventilation approaches, there was no

Table 1:
Participants' characteristics. Totals may not equal 100 due to rounding.

Characteristic		Participants (n = 68)
Sex, n (%)	Male	38 (55.9%)
	Female	29 (42.7%)
	Other	1 (1.5%)
Profession, n (%)	Paramedic	57 (83.8%)
	Emergency medical technician	9 (13.2%)
	Nurse	2 (2.9%)
Age, median [Q1–Q3]		33 [28; 38]
Years since diploma, median [Q1–Q3]		5 [2; 11]
Prehospital work experience in years, median [Q1–Q3]		8 [4; 15]
Emergency medical service, n (%)	*Genève TEAM Ambulances*	16 (23.5%)
	Centre de Secours et d'Urgence de la Ville de Sion	6 (23.5%)
	SK Ambulances	12 (17.7%)
	Ambulances des Vallées Neuchâteloises	6 (8.8%)
	SIS des Montagnes Neuchâteloises	6 (8.8%)
	ACE Genève Ambulances	4 (5.9%)
	SAG Secours Ambulances Genève	4 (5.9%)
	SPS Neuchâtel	4 (5.9%)
Actual number of paediatric out-of-hospital cardiac arrests responded to, median [Q1–Q3].		0 [0; 1]
Estimated elapsed time since last paediatric out-of-hospital cardiac arrest in the field, n (%)	No prior paediatric resuscitation in the field	35 (51.5%)
	<6 months	2 (2.9%)
	6–12 months	1 (1.5%)
	12–24 months	10 (14.7%)
	>24 months	20 (29.4%)
Estimated elapsed time since last simulated paediatric out-of-hospital cardiac arrest, n (%)	No prior simulated paediatric resuscitation	5 (7.4%)
	<6 months	12 (17.7%)
	6–12 months	13 (19.1%)
	12–24 months	13 (19.1%)
	>24 months	25 (36.8%)
Specific post-graduate course in paediatric out-of-hospital cardiac arrest, n (%)		38 (55.9%)

SIS: Service d'Incendie et de Secours: SPS: Service de la protection et de la sécurité

clinically relevant difference in the primary outcome when an intermediate airway management strategy was used, with an increase of only 36 ml/min in alveolar ventilation. However, the wide 95% CI (−28 to 99 ml) surrounding this point estimate suggests considerable variability, and the clinical relevance may vary significantly depending on the actual value of the parameter. These findings underscore the need for a critical evaluation of the observed differences and their potential impact on clinical decisions and patient outcomes. Increasing the sample size to achieve ad-

Figure 2: Comparison of alveolar ventilation (ml/min) between Bag-Valve-Mask (BVM) and Intermediate Airway Management (IAM) strategies. Each line connects the data points for individual teams, highlighting changes in alveolar ventilation from BVM to IAM.

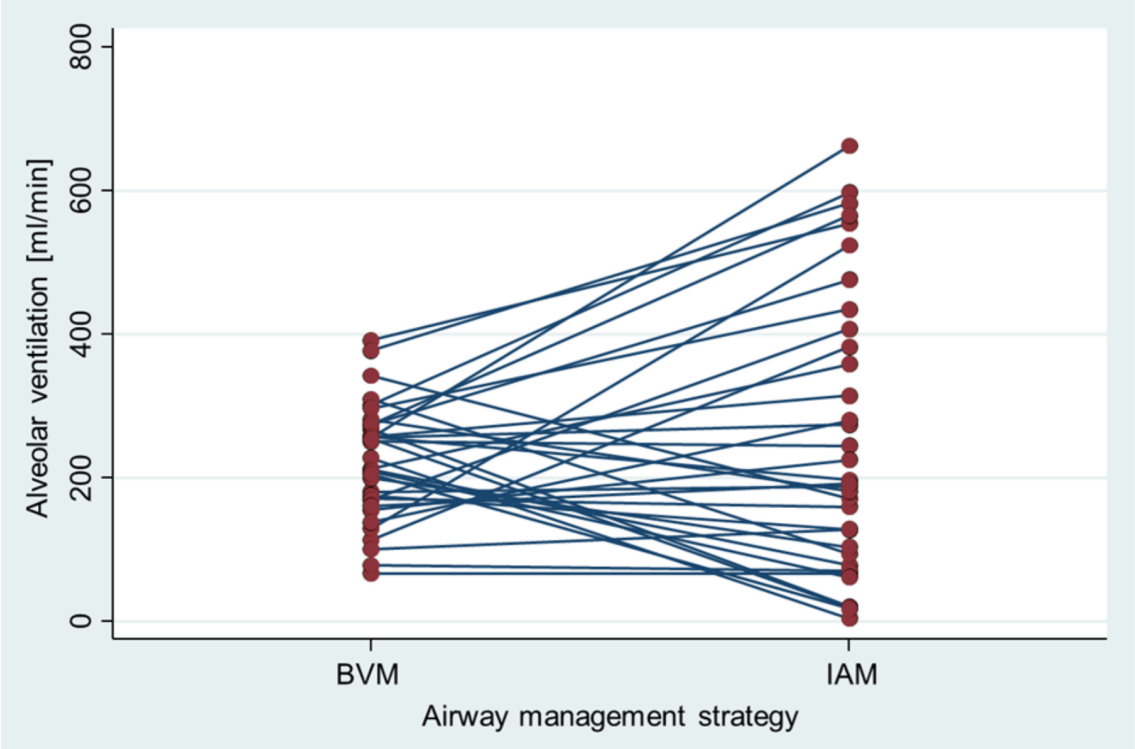


Table 2:
Ventilation outcomes. Totals may not equal 100 due to rounding.

		Bag-valve-mask	Intermediate airway management	Difference
Number of ventilations, mean (95% CI)		79 (74 to 84)	96 (89 to 103)	−17 (−23 to −10)
Ventilation volume in ml, mean (95% CI)		54 (51 to 58)	53 (45 to 61)	1 (−7 to 10)
Time to first ventilation in s, median [Q1–Q3]		49 [36; 65]	72 [53; 98]	−27 [−48; −1]
% of ventilations below/within/over target volume, mean (95% CI)	Below (<45 ml)	39 (32 to 45)	47 (35 to 59)	−8 (−20 to 3)
	Within (45–72 ml)	38 (34 to 42)	28 (22 to 35)	9 (2 to 16)
	Over (>72 ml)	23 (19 to 28)	24 (14 to 35)	−1 (−11 to 9)

Table 3:
Chest compression outcomes. Totals may not equal 100 due to rounding.

		Bag-valve-mask	Intermediate airway management	Difference
Chest compression fraction in %, mean (95% CI)		58 (56 to 60)	70 (68 to 73)	−12 (−15 to −11)
Compression rate in cpm, mean (95% CI)		124 (121 to 127)	123 (121 to 126)	0 (−1 to 2)
% of compressions below/within/over target rate, mean (95% CI)	Below (<100 cpm)	1.0 (0.6 to 1.4)	1.0 (0.4 to 1.5)	0 (−0.5 to 0.5)
	Within (100–120 cpm)	38 (27 to 49)	37 (26 to 48)	1 (−4 to 7)
	Over (>120 cpm)	61 (49 to 72)	62 (51 to 73)	−1 (−7 to 4)
Compression depth in cm, median [Q1–Q3]		3.0 [2.9; 3.2]	2.9 [2.8; 3.1]	0 [−0.8; 2.0]
% of compressions below/within guideline's depth target, median [Q1–Q3]	Below (<4.3 cm)	100 [100; 100]	100 [100; 100]	0 [0; 0]
	Within (≥4.3 cm)	0 [0; 0]	0 [0; 0]	0 [0; 0]
% of compressions below/within/over manufacturer's depth target, median [Q1–Q3]	Below (<4 cm)	100 [98; 100]	100 [97; 100]	0 [0; 1]
	Within (4–5 cm)	0 [0; 2]	0 [0; 3]	0 [0; 0]
	Over (>5 cm)	0 [0; 0]	0 [0; 0]	0 [0; 0]
Complete chest recoil, %, median [Q1–Q3]		58 [45; 74]	46 [30; 56]	13 [3; 26]

cpm: compressions per minute.

equate statistical power would not enhance the clinical impact of such a small difference in alveolar ventilation. This lack of difference aligns with the Amagasa et al. meta-analysis, which showed that prehospital advanced or intermediate airway management (including both endotracheal intubation and supraglottic airway) for paediatric out-of-hospital cardiac arrest did not improve outcomes compared to bag-valve-mask. Their ranking analysis indicated that bag-valve-mask was superior to supraglottic airway and endotracheal intubation for survival and favourable neurological outcomes, with a low to very low level of certainty [59].

Suboptimal paediatric CPR approach

All groups displayed a suboptimal approach to paediatric CPR by prioritising defibrillation pad placement over ventilation, following the adult approach. This was unexpected since prehospital providers are taught to tailor resuscitation

Table 4:
Timing of adrenaline administration.

		Intermediate airway management		
		Not administered	**Administered**	**Total**
Bag-valve-mask	Not administered	1	2	3
	Administered	5	26	31
	Total	6	28	34

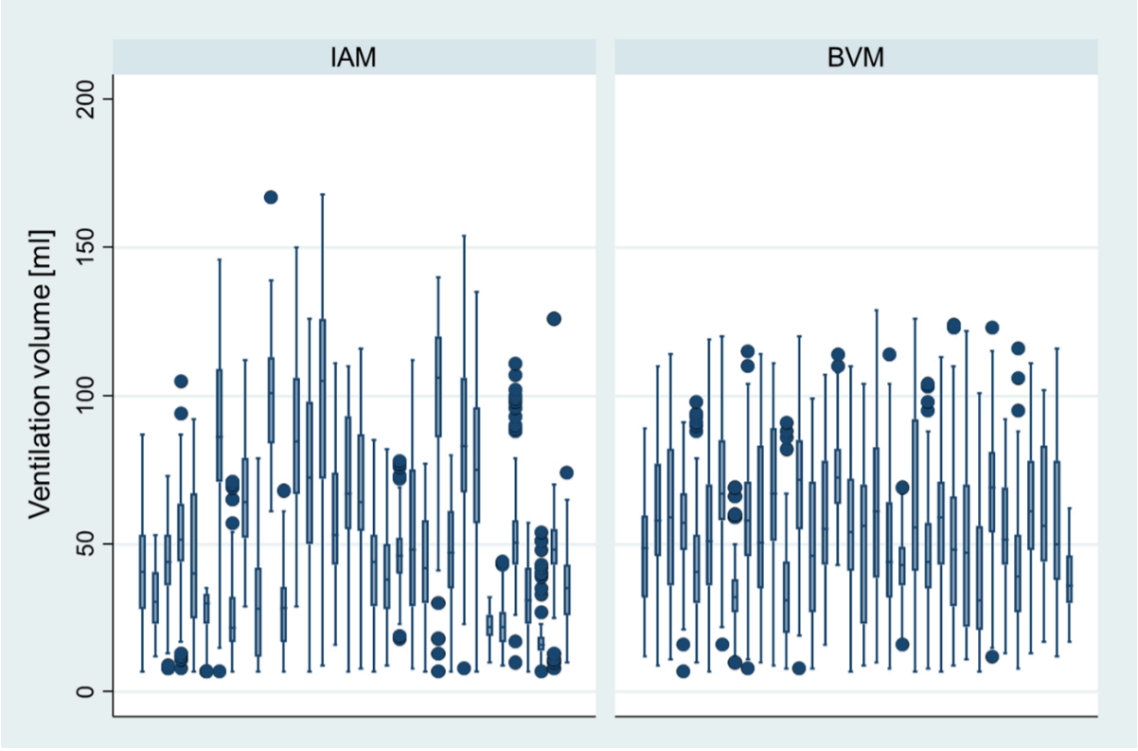
Table 5:
Timing of adrenaline administration within 5 minutes.

		Intermediate airway management		
		After 5 minutes	**Within 5 minutes**	**Total**
Bag-valve-mask	After 5 minutes	31	2	33
	Within 5 minutes	1	0	1
	Total	32	2	34

Table 6:
Number of ventilations below/within/over target volume, n (%). Totals may not equal 100 due to rounding.

	Bag-valve-mask	**Intermediate airway management**
<45 ml	1058 (39.8%)	1573 (48.3%)
45–72 ml	1023 (35.0%)	941 (28.9%)
>72 ml	606 (22.6%)	743 (22.8%)

Figure 3: Scaled analysis of ventilation volume per team (the same team corresponding to the same boxplot, e.g. the first boxplot in the Intermediate Airway Management [IAM] graph represents the data from the same team as the first boxplot in the Bag-Valve-Mask [BVM] graph). The box represents the interquartile range (IQR), which spans from the first quartile (Q1, 25th percentile) to the third quartile (Q3, 75th percentile). The line inside the box indicates the median (Q2, 50th percentile). The whiskers extend to the smallest and largest values within 1.5 times the IQR from Q1 and Q3, respectively. Data points outside this range are considered outliers and are represented as individual dots.



to children's specific needs by prioritising effective ventilation over pad placement. However, the time to first ventilation was relatively low (49 s for bag-valve-mask and 72 s for intermediate airway management) compared to simulated cases with larger CPR teams, where the time to first bag-valve-mask ventilation was 1.4 or 1.5 minutes depending on whether the cardiac rhythm was shockable [60]. It is important to note that the timing of different airway management interventions does not appear to affect patient outcomes [61]. On the other hand, a shorter time to first adrenaline dose was found in larger team responses [60], possibly due to different prioritisation strategies.

Variability in ventilation volumes using the i-gel®

Another notable finding was the increased variability in ventilation volumes with the i-gel®, accompanied by a higher proportion of hyperinflation. Continuous chest compressions during intermediate airway management may have made self-assessment of ventilatory quality (by visualising chest rise) difficult compared to using a bag-valve-mask device. It is unclear to what extent the lack of sealing, linked to the fact that the use of a manikin prevents the gel cuff from reaching an adequate seal pressure, could impact this endpoint. Indeed, the seal pressure appears to improve over time in humans due to the thermoplastic properties [62]. Moreover, it is uncertain whether the measures of compression and ventilation parameters were reliable when performing continuous compressions with asynchronous ventilations using a non-tracheal device. The clinical impact of this variability should be questioned. Participant exposure to simulated or actual cases was very low. While 20 insertions are recommended for novices to develop skills in using the i-gel® [63], it remains unclear how to maintain the skill. More recent simulation, increased participation and simulation training during daytime hours may improve CPR performance [64]. The observed variability could likely be mitigated with continuous training and/or quality management. Hyperventilation occurs more often during CPR with a tracheal tube or a supraglottic airway in place than with a bag-valve-mask. Given the limited data on the impact of ventilation parameters on clinical outcomes in paediatric out-of-hospital cardiac arrest, future research should focus on respiratory physiology during paediatric CPR to determine the optimal ventilation rate [65]. Two potential solutions to mitigate higher variability in clinical settings include using ventilation feedback devices and/or using an i-gel® without continuous chest compressions, similar to bag-valve-mask with a 15:2 ratio, as this will still improve the chest compression fraction [41].

Clinical implications

Prehospital providers should consider that impaired lung compliance can make bag-valve-mask use more difficult by increasing air leaks. Therefore, devices and strategies should be selected based on the clinical situation. The lack of clinically relevant differences between bag-valve-mask and intermediate airway management observed in the present study, and the higher odds ratios for survival associated with bag-valve-mask compared to intermediate airway management or advanced airway management in a registry-based American study [66], advocate for the use of bag-valve-mask as the first-line oxygenation tool in cases of paediatric out-of-hospital cardiac arrest. This is in line with the 2024 Internation Liaison Committee on Resuscitation Consensus on Science with Treatment Recommendations [67]. However, intermediate airway management could be useful when bag-valve-mask use is difficult and should not be entirely disregarded since ventilation was improved after supraglottic airway insertion in 96/135 (71%) of cases [68]. Moreover, a Japanese study reported no significant difference in one-month survival between prehospital endotracheal intubation and supraglottic airway insertion by emergency medical service personnel among paediatric out-of-hospital cardiac arrest patients [69], suggesting that emergency medical service personnel may rely on their familiar strategy when performing more advanced prehospital airway management during paediatric out-of-hospital cardiac arrest. These assertions should, to the extent possible, be confirmed by sufficiently powered randomised controlled trials.

Chest compressions metrics

The difference in chest compression fraction (favouring intermediate airway management) and chest recoil (favouring bag-valve-mask) suggests that neither approach was conclusively superior. Compressions were consistently too shallow in both groups. Regarding compression quality metrics, and especially compression depth, our results were similar to actual in-hospital cardiac arrests. Quality metrics often did not meet the guidelines, with the greatest difficulty in achieving the chest compression depth target in younger children (for children less than 1 year only, median [Q1–Q3] chest compression fraction was 88% [61; 98], rate was 119/min [110; 129] and depth 2.3 cm [1.9; 3.0]) [70]. The compression technique (thumbs/one hand/two hands) was not assessed in this study but could partly explain the results as different hand positions during CPR in young children have been shown to change compression depth [71]. Finally, the high cognitive load experienced by participants during paediatric out-of-hospital cardiac arrest [72] could explain a lower CPR quality in paediatric cases compared to adults [60].

Strengths and limitations

This study has limitations. It was underpowered, due to an error in the sample size calculation, as detailed previously, which may have impacted the robustness of our findings and the generalisability of our conclusions. A possible bias was noted with an automatically displayed end-tidal CO_2 value on the monitor even if ventilation was at 0 ml/min, which we found concerning for high-fidelity manikins. All scenarios were simulated and thus cannot be directly linked to clinical outcomes, potentially not accurately reflecting real-life resuscitation quality. The use of simulation was essential due to the infrequency of paediatric out-of-hospital cardiac arrest cases. Performance was likely superior to real-life scenarios due to the controlled environment and reduced stress, and a Hawthorne effect cannot be ruled out [73].

Despite these limitations, the study's strong design i.e. the crossover design which controls for static confounders, the multicentric setting and the adherence to a published protocol represent clear strengths. The data generated provides

valuable insights into the challenges and considerations surrounding paediatric ventilation in prehospital settings.

Conclusions

In a simulated paediatric out-of-hospital cardiac arrest model, a strategy of immediate intermediate airway management use without prior bag-valve-mask ventilations did not result in relevant differences. Thus, intermediate airway management devices cannot be recommended as first-line devices for paediatric out-of-hospital cardiac arrest but should be considered when bag-valve-mask oxygenation is challenging, particularly when lung compliance is altered. Overall, the focus should remain on providing high-quality ventilations regardless of the device used by emergency medical services providers.

Data availability statement

The datasets supporting the results of this article are available on a Yareta repository (https://doi.org/10.26037/yareta:cyekjdvz75cdba4p3ifxjae6zm).

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Potential competing interests

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