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Clinical paper

## Performance of the i-gel<sup>TM</sup> during pre-hospital cardiopulmonary resuscitation<sup>\*</sup>

### David Häske<sup>a,\*</sup>, Benjamin Schempf<sup>b</sup>, Gernot Gaier<sup>c</sup>, Christoph Niederberger<sup>c</sup>

<sup>a</sup> Emergency Medical Service, German Red Cross, Obere Wässere 1, 72764 Reutlingen, Germany

<sup>b</sup> Department of Internal Medicine, Cardiology, Angiology and Intensive Care Medicine, Klinikum am Steinenberg, Steinenbergstrasse 31, 72764 Reutlingen, Germany

<sup>c</sup> Department of Anaesthesiology and Intensive Care Medicine, Klinikum am Steinenberg, Steinenbergstrasse 31, 72764 Reutlingen, Germany

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#### ABSTRACT

*Background:* Current cardiopulmonary resuscitation (CPR) guidelines recommend airway management and ventilation whilst minimising interruptions to chest compressions. We have assessed i-gel<sup>TM</sup> use during CPR.

*Methods:* In an observational study of i-gel<sup>TM</sup> use during CPR we assessed the ease of i-gel<sup>TM</sup> insertion, adequacy of ventilation, the presence of a leak during ventilation, and whether ventilation was possible without interrupting chest compressions.

*Results*: We analysed i-gel<sup>TM</sup> insertion by paramedics (n = 63) and emergency physicians (n = 7) in 70 prehospital CPR attempts. There was a 90% first attempt insertion success rate, 7% on the second attempt, and 3% on the third attempt. Insertion was reported as easy in 80% (n = 56), moderately difficult in 16% (n = 11), and difficult in 4% (n = 3). Providers reported no leak on ventilation in 80% (n = 56), a moderate leak in 17% (n = 12), and a major leak with no chest rise in 3% (n = 2). There was a significant association between ease of insertion and the quality of the seal (r = 0.99, p = 0.02). The i-gel<sup>TM</sup> enabled continuous chest compressions without pauses for ventilation in 74% (n = 52) of CPR attempts. There was no difference in the incidence of leaks on ventilation between patients having continuous chest compressions and patients who had pauses in chest compressions for ventilation (83% versus 72%, p = 0.33, 95% CI [-0.1282, 0.4037]). Ventilation during CPR was adequate during 96% of all CPR attempts.

*Conclusions:* The i-gel<sup>™</sup> is an easy supraglottic airway device to insert and enables adequate ventilation during CPR.

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#### 1. Introduction

There are numerous airway and ventilation techniques that can be used during pre-hospital cardiopulmonary resuscitation (CPR). Acquiring the skills needed requires training and on-going practice with the available techniques. This applies to both bagmask ventilation and tracheal intubation.<sup>1,2</sup> Current CPR guideline recommends that only those skilled and experienced in the technique perform tracheal intubation.<sup>2</sup> Although individual abilities will vary, studies show that 50–100 tracheal intubations must be performed to develop proficiency followed by regular practice to maintain it.<sup>3–5</sup>

In the emergency medical service (EMS) district of Reutlingen (in southern Germany), we decided that paramedics use a supraglottic

E-mail address: haeske@rettungsdienst-reutlingen.de (D. Häske).

airway device (SAD) as the first airway intervention during CPR instead of bag-mask ventilation and incorporated this into our local standard operating procedures.<sup>6</sup> We therefore assessed the use of the i-gel during CPR, as there are few CPR studies of i-gel use in real patients. Despite this, the i-gel is currently considered equivalent to other SADs for use during CPR and included in current guidelines.<sup>7</sup>

The i-gel<sup>TM</sup> (Intersurgical) consists of a solid flexible tube and cuff (Fig. 1). The main difference from other SADs is the non-inflatable cuff. The cuff is made of a thermoplastic gel-like elastomer, and the shape is designed to fit the laryngeal structures and form a seal (Fig. 2).

Supraglottic airway devices are generally regarded as effective during resuscitation.<sup>8</sup> Moreover, manikin studies show that ventilation with a SAD during CPR compares favourably to bagmask-ventilation.<sup>9,10</sup> To date, there are only two observational case series of i-gel use during CPR.<sup>11,12</sup>

The aim of this observational study is to assess the use of the i-gel during pre-hospital CPR, specifically the ease of insertion, adequacy of ventilation, the presence of a leak on ventilation, and whether ventilation is possible without interrupting chest compressions.

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\* Corresponding author.

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Fig. 1. The i-gel<sup>™</sup>, a supraglottic airway device.

#### 2. Methods

#### 2.1. Study design and preparation

This study was designed as a non-randomised, single centre prospective observational study. The data were collected in the EMS of Reutlingen (Germany). The local ethics committee approved the study.

#### 2.2. Providers

The providers were paramedics and emergency physicians who had taken a 2-h hands-on training session on i-gel use during CPR. The i-gel was used as the first airway device during CPR without any preceding bag-mask ventilation. Manufacturer's recommendations were followed regarding the size of i-gel inserted.

#### 2.3. Patient population

The study included adult patients with any cause of pre-hospital cardiac arrest attended by the EMS and who had a CPR attempt. Patients with traumatic brain injury were excluded.



**Fig. 2.** CT image with a placed i-gel<sup>TM</sup> at the level of the larynx (courtesy of the Institute for Radiology, Klinikum am Steinenberg, Reutlingen, Germany).

#### 2.4. Data sources and measurements

A standardised protocol was used to collect the data at the scene. Clinical (and subjective) measures of ventilation, leak, and insertion success were collected by rescuers during patient treatment. In addition, we counted the number of insertion attempts required, measured the patient's height, and estimated the patient's weight based on available medical records and information from relatives. We used the presence of visible chest rise and the fogging of the igel tube to indicate adequate ventilation. Insertion success and the presence of a leak on ventilation were assessed subjectively by rescuers. A moderate leak was defined as an air leak that still enabled sufficient ventilation. A major leak occurred when ventilation was not possible and no chest rise was seen during ventilation attempts.

In addition, after i-gel insertion and during CPR we recorded the highest end-tidal carbon dioxide value using mainstream technology, and oxygen saturation value with a finger probe. Rescuers also subjectively assessed whether continuous chest compressions during ventilation with the i-gel could be provided effectively.

#### 2.5. Statistical methods

The chi-square test was used to compare the differences in ventilation with or without on-going chest compressions. Pearson's product-moment correlation was used to compare leak and insertion success with the i-gel. *p*-Values < 0.05 were considered to be significant. Descriptive statistics are expressed as mean  $\pm$  standard deviation. All statistical analyses were conducted with BiAS (Version 10, epsilon-Verlag, Germany).

#### 3. Results

# 3.1. Descriptive statistics about the providers and the patient population

We analysed 70 cases of i-gel insertion during CPR. The study period was 1 September 2010–31 November 2011. The mean age of the patients was  $70 \pm 11$  years, the mean estimated weight was  $84 \pm 13$  kg, and the mean height was  $174 \pm 7$  cm.

Ninety percent (n = 63) of i-gel insertions were by paramedics, and 10% (n = 7) were by emergency physicians. The mean age of the paramedics was  $36 \pm 8$  years. Their mean work experience was  $12 \pm 6$  years. The average mean age of physicians was  $39 \pm 11$  years; their work experience was  $11 \pm 7$  years.

It was possible to insert the i-gel in all patients. Ninety per cent of insertions were successful on the first attempt, 7% on the second attempt, and 3% on the third attempt. The rescuer did not change between insertion attempts. Most insertions (80%, n = 56) were rated as easy, 16% (n = 11) as moderately difficult, and 4% (n = 3) difficult. Similarly, rescuers rated leaks on ventilation as no leak in 80% (n = 56), moderate leak in 17% (n = 12), and a major leak not enabling ventilation in 3% (n = 2). There was a statistically significant relationship between the ability to place the device and the presence of a leak (r = 0.99, p = 0.02).

#### 3.2. Ventilation

Most (91%, n = 64) of patients were judged to have adequate ventilation. In another 4 cases ventilation was possible albeit with a leak and the i-gel was changed to an alternate airway. In two patients, no ventilation with the i-gel was possible. Of note, these two were the only patients reported to have evidence of regurgitation of gastric contents on EMS arrival.



Fig. 3. Leak on ventilation in patients who received continuous chest compressions or chest compressions with interposed ventilation.

# 3.3. Feasibility of continuous chest compressions during ventilation

The i-gel enabled continuous chest compressions without pauses for ventilation in 74% (n = 52) of CPR attempts. There was no statistically significant difference in terms of leaks during ventilation (no leak versus moderate leak) between patients on whom chest compressions were performed continuously and patients who received chest compressions with interposed ventilation (83% versus 72%, p = 0.33, 95% CI [-0.1282, 0.4037]) (Fig. 3). Using our definition, in most patients (96%) it was possible to provide adequate ventilation during CPR, even when a moderate leak was present.

Of the patients, 46% (n=32) had tracheal intubation at some stage after i-gel insertion. Among these patients, 23 patients were ventilated with the i-gel with no leak on ventilation.

After the insertion of the i-gel, mean oxygen saturation  $(SpO_2)$  during CPR was 90% (range: 76–100%); the end-tidal carbon dioxide (etCO<sub>2</sub>) was 27 mmHg (range: 9–46 mmHg). The presence of a leak during ventilation made only a small difference to oxygen saturation and end-tidal carbon dioxide (Table 1).

#### 3.4. i-gel-sizes

A size 3 i-gel was used for 3 insertions, a size 4 for 39 insertions, and size 5 for 28 insertions. There was no leak during ventilation with a size 3 i-gel in 2 insertions, size 4 in 32 insertions and size 5 in 22 insertions (Table 2). The mean estimated weight of patient's who had a size 3 i-gel inserted was 65 kg (range: 60–70 kg) (manufacturer's recommendation 30–60 kg), 80.6 kg (range: 60–110 kg) for a size 4 (manufacturer's recommendation 50–90 kg), and 94.6 kg (range: 70–160 kg) for a size 5 (manufacturer's recommendations 90+ kg) (Fig. 4).

i-gel size and the presence of a moderate leak on ventilation is summarised in Table 3. Mean weight for size 3 was 50 kg (n=1), size 4 was 67.8 kg (n=7) and size 5 was 100 kg (n=6). The i-gel which were not tight were also in the range of the manufacturer's

**Table 1** SpO<sub>2</sub> and etCO<sub>2</sub> for i-gel<sup>TM</sup> seals considered "no leak" and "moderate leak.".

		Mean	Minimum	Maximum
SpO <sub>2</sub>	No leak	90%	76%	100%
	Moderate leak	87%	83%	94%
etCO <sub>2</sub>	No leak	27 mmHg	9 mmHg	46 mmHg
	Moderate leak	20 mmHg	10 mmHg	30 mmHg





purpose. There is no direct correlation between the i-gel-sizes and the leak or the no leak on ventilation group (p = 0.54).

Mean body mass index for tight i-gel size 3 was  $24.7 \pm 3.7 \text{ kg/m}^2$  (range: 22.0–27.3), size 4 was  $26.9 \pm 2.8 \text{ kg/m}^2$  (range: 20.8–31.2), and size 5 was  $29.3 \pm 7.2 \text{ kg/m}^2$  (range: 23.1–49.3). Mean body mass index for summarised not-tight i-gel size 3 was  $19.5 \text{ kg/m}^2$ , size 4 was  $24.3 \pm 2.3 \text{ kg/m}^2$  (range: 22.3 – 27.5), and size 5 was  $32.2 \pm 8.3 \text{ kg/m}^2$  (range: 24.7–46.7).

#### 4. Discussion

In our prehospital EMS system, we have observed successful use of the i-gel by paramedics and physicians during CPR. In addition continuous chest compressions could be performed without pauses for ventilation, after i-gel insertion.

Published data on the use of the i-gel during CPR is sparse. Initial experiences with the i-gel in pre-hospital CPR in 12 patients showed that it was simple to insert, but ventilation was inadequate in 58% of the patients.<sup>12</sup> In contrast, in-hospital data from 100 i-gel insertions during CPR reported that insertion was easy in 83%, and needed only one attempt in 82%.<sup>11</sup> The i-gel could not be inserted in only one patient. In 61% of the patients, continuous chest compressions were possible. In 59%, there were no leaks on ventilation. In 39% despite a leak ventilation was judged as adequate. Our findings in the prehospital setting closely agree with these previous in-hospital findings showing the i-gel is easy to place successfully, without the need for extensive training. Moreover, the seal is good enough to ensure adequate ventilation in most cases of cardiac arrest. Of note two patients out of 70 could not be ventilated after igel insertion. Both patients had evidence of regurgitation of gastric contents before EMS arrival. In these two cases pharyngeal soiling may have led to an inadequate cuff position, or lung injury from aspiration may have led to higher airway pressures and ineffective ventilation

Our results show that an easier reported i-gel insertion correlated with fewer leaks during ventilation. In addition we observed that a size 4 or size 5 i-gel was suitable for most adults, and that the manufacturer's recommended weight ranges were appropriate. The victim's height and body mass index did not appear to be relevant when choosing the i-gel size.

We assessed oxygen saturation  $(SpO_2)$  and end-tidal carbon dioxide  $(etCO_2)$  during CPR after i-gel insertion. These measures are not influenced solely by oxygenation and ventilation during CPR and therefore cannot be used to make any firm conclusions about adequacy of ventilation with the i-gel during CPR.

Recent observational data from Japan questions the role of advanced airway techniques in patients with out-of-hospital cardiac arrest.<sup>13</sup> Observational data from 649,359 patients showed that bag-mask ventilation was associated with improved survival and neurological outcomes compared to both SADs and tracheal

Table 2					
i-gel size used, patient's estimated weight, height, body mass index and the manufacturer's recommendation for i-gel size.					
<u> </u>	NY 1				

Size	Number	Weight (kg) (range)	Height (cm) (range)	Body mass index (kg/m <sup>2</sup> ) (range)	Manufacturer's recommendation (kg)
3	3	$65\pm7.0(6070)$	$162.5\pm 3.5(160175)$	$24.7 \pm 3.7  (22.027.3)$	30-60
4	39	80.6 ± 11.6 (60-110)	$173 \pm 8.6  (150 - 195)$	26.9 ± 2.8 (20.8-31.2)	50-90
5	28	$94.6 \pm 23.0  (70160)$	$179.7\pm4.6(160190)$	$29.3 \pm 7.2  (23.1  49.3)$	90+

#### Table 3

Size	Applications	Weight (kg) (range)	Height (cm) (range)	Body mass index (kg/m <sup>2</sup> ) (range)	Manufacturer's recommendations (kg)
3	1	50	160	19.5	30-60
4	7	67.8 (59-80)	166.8 (161–175)	$24.3 \pm 2.3 (22.3 - 27.5)$	50-90
5	6	100(60-120)	178.3 (150-190)	$32.2 \pm 8.3 \ (24.7 - 46.7)$	90+

intubation. Both these and our findings need to be confirmed by large randomised controlled studies as most of the evidence for airway interventions during CPR is based on observational data.

#### 5. Limitations

Our findings relating to adequate ventilation and leak were based on the subjective views of rescuers. Adequate ventilation was defined as visible chest rise and fogging of the i-gel and we did not assess tidal volumes. It is also possible that only those in whom continuous chest compressions and ventilation were feasible actually had this recorded, and those patients in whom this technique was not possible, had standard CPR with a pause for ventilation after every 30 compressions. A major limitation is that our study is too small and not designed to assess whether i-gel use actually improves or worsens patient survival and neurological function. Finally, we must question whether the use of a new tool led to an unconscious improvement in outcome during a "honeymoon period" and the fact that we were measuring the process led to better outcomes (Hawthorne effect).

#### 6. Conclusions

Our observational data show that the i-gel is an easy supraglottic airway device to insert and enable adequate ventilation during CPR. Little training is needed to become proficient in its use. In most cases, continuous chest compressions are possible during ventilation with the i-gel, thus reducing interruptions to chest compression.

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#### **Conflict of interest statement**

All authors confirm that they have received neither governmental nor industrial financial support that could influence this work.

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#### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.resuscitation.2013.04.025.

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