

MDPI

Article

Dependence of Successful Airway Management in Neonatal Simulation Manikins on the Type of Supraglottic Airway Device and Providers' Backgrounds

Takahiro Sugiura ^{1,2,*}, Rei Urushibata ^{2,3}, Satoko Fukaya ⁴, Tsutomu Shioda ², Tetsuya Fukuoka ² and Osuke Iwata ^{1,4}

- Department of Pediatrics and Neonatology, Toyohashi Municipal Hospital, 50 Aza Hakken Nishi, Aotake-cho, Toyohashi 441-8570, Japan; o.iwata@med.nagoya-cu.ac.jp
- Department of Pediatrics and Neonatology, Shizuoka Saiseikai General Hospital, Shizuoka 422-8527, Japan; rei-urushi@ncnp.go.jp (R.U.); t166294@siz.saiseikai.or.jp (T.S.); t162795@siz.saiseikai.or.jp (T.F.)
- Department of Pediatrics, Hamamatsu University School of Medicine, Hamamatsu 431-3192, Japan
- Center for Human Development and Family Science, Department of Pediatrics and Neonatology, Nagoya City University Graduate School of Medical Sciences, 1 Kawasumi, Mizuho, Nagoya 467-8601, Japan; sfukaya@med.nagoya-cu.ac.jp
- * Correspondence: sugiura-takahiro@toyohashi-mh.jp

Abstract: Supraglottic airway devices such as laryngeal masks and i-gels are useful for airway management. The i-gel is a relatively new device that replaces the air-inflated cuff of the laryngeal mask with a gel-filled cuff. It remains unclear which device is more effective for neonatal resuscitation. We aimed to evaluate the dependence of successful airway management in neonatal simulators on the device type and providers' backgrounds. Ninety-one healthcare providers performed four attempts at airway management using a laryngeal mask and i-gel in two types of neonatal manikins. The dependence of successful insertions within 16.7 s (75th percentile of all successful insertions) on the device type and providers' specialty, years of healthcare service, and completion of the neonatal resuscitation training course was assessed. Successful insertion (p = 0.001) and insertion time (p = 0.003) were associated with using the i-gel vs. laryngeal mask. The providers' backgrounds were not associated with the outcome. Using the i-gel was associated with more successful airway management than laryngeal masks using neonatal manikins. Considering the limited effect of the provider's specialty and experience, using the i-gel as the first-choice device in neonatal resuscitation may be advantageous. Prospective studies are warranted to compare these devices in the clinical setting.

Keywords: airway management; health occupations; laryngeal mask; newborn; resuscitation



Citation: Sugiura, T.; Urushibata, R.; Fukaya, S.; Shioda, T.; Fukuoka, T.; Iwata, O. Dependence of Successful Airway Management in Neonatal Simulation Manikins on the Type of Supraglottic Airway Device and Providers' Backgrounds. *Children* 2024, 11, 530. https://doi.org/ 10.3390/children11050530

Academic Editor: Joaquim M. B. Pinheiro

Received: 13 March 2024 Revised: 24 April 2024 Accepted: 25 April 2024 Published: 28 April 2024



Copyright: © 2024 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https://creativecommons.org/licenses/by/4.0/).

1. Introduction

Although most newborn infants successfully transition from intrauterine to extrauterine life without special help, approximately one in ten newborn infants require some form of medical assistance before spontaneous breathing is successfully established, and approximately 1 in 100 newborn infants require extensive cardiopulmonary resuscitation [1]. Positive pressure ventilation plays a pivotal role in neonatal resuscitation, given that respiratory failure typically precedes cardiac failure in newborn infants. Ineffective positive-pressure ventilation over prolonged periods could lead to the need for advanced resuscitation, including intubation, chest compressions, and adrenaline administration. Notably, every 30 s delay in initiating efficient ventilation is associated with a 16% increase in the risk of mortality or morbidity [2]. However, the optimal interface for administering positive pressure ventilation during the initial stages of resuscitation remains unclear.

Bag-and-mask ventilation is the most common form of positive-pressure ventilation [1]. Although a correctly executed bag-and-mask procedure offers ventilation comparable to that achieved with a tracheal tube, this technique requires training and experience. Similarly,

Children **2024**, 11, 530

tracheal tube intubation inherently involves a balance between the potential benefits and risks. A comprehensive registry study encompassing over 2600 intubation episodes in academic neonatal units highlighted significant challenges: severe oxygen desaturation, defined as a reduction of 20% or more from baseline oxygen saturation levels, in 41% of these episodes [3]. Successful intubation on the first attempt occurred in only half of the patients. A multivariable analysis within the registry study revealed that an increasing number of intubation attempts was correlated with a significantly heightened risk of adverse events (adjusted odds ratio [OR] 1.87, 95% confidence interval [CI] 1.63–2.14). Clinicians must consider alternative methods after an initial unsuccessful intubation attempt to avoid escalating the risk of harm through repeated failed attempts.

Laryngeal masks and other types of supraglottic airway devices are increasingly used for neonatal resuscitation. Global practice guidelines recommend the use of supraglottic airway devices for resuscitation of term and preterm newborns delivered \geq 34 weeks gestation when tracheal intubation is not successful or feasible [1]. Furthermore, a recent study on late preterm and term infants reported that the time to spontaneous breathing was shorter with the use of supraglottic airway devices than with a face mask [4]. Consequently, the current guidelines suggest that supraglottic airway devices may be used in the place of face masks for newborns receiving positive pressure ventilation after delivery if the resources and training are available [5].

Since the introduction of the first laryngeal mask in 1983 [6], many revisions have been made to supraglottic airway devices to improve the safety and efficacy of airway management [7]. While the classical laryngeal mask must be inflated before use, the i-gel (Intersurgical Ltd., Wokingham, Berkshire, UK) has improved utility by replacing the air-inflatable cuff with a gel-filled ergonomic cuff (Figure 1).

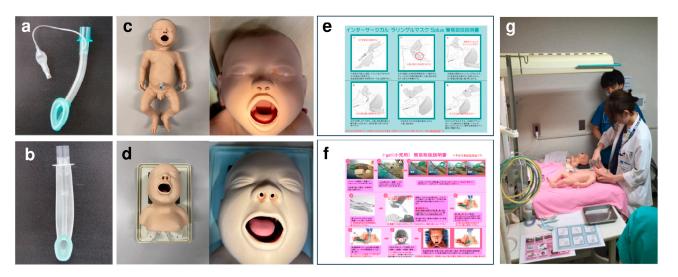


Figure 1. Supraglottic airway devices used and study procedure. Laryngeal mask (a), i-gel (b), Koken Neonatal Resuscitation Model LM-089 (c), Laerdal neonatal intubation trainer (d), one-page instructions for the laryngeal mask (e) and the i-gel (f) (original Japanese instructions see Supplemental Materials), and actual study procedure using two types of manikins and two different supraglottic airway devices (g).

Several studies have compared the effectiveness of laryngeal masks and i-gels in anesthetized children and found similar success rates [8–15]. However, studies have reported conflicting findings regarding insertion time. Several studies have demonstrated that the insertion time was shorter with the i-gel than with a laryngeal mask [8,10,14], whereas other studies reported similar [9,11] or longer [12,13,15] insertion times with the i-gel than with a laryngeal mask. Considering that the backgrounds of the patients and providers differed between these studies, these conflicting findings suggest that the effectiveness of airway management using a laryngeal mask and i-gel varies according to

Children 2024, 11, 530 3 of 11

the patient type, procedure (resuscitation or anesthesia), and the provider's background. Furthermore, these studies focused on airway management in children undergoing general anesthesia; therefore, little is known about airway management in newborn infants who need to be resuscitated shortly after birth. With further information on the dependence of successful airway management on the type of supraglottic airway device, background of newborn infants, and experience of resuscitation providers, the quality and efficacy of neonatal resuscitation may be significantly improved.

This study aimed to assess the dependence of successful laryngeal mask and i-gel insertion on the specialty, career, and experience of the resuscitation provider using neonatal simulation manikins.

2. Materials and Methods

This was a crossover randomized trial using two types of supraglottic airway devices in two types of neonatal simulation manikin. The study protocol was approved by the Institutional Review Board of Shizuoka Saiseikai General Hospital (#20231601). Participants were recruited from healthcare professionals who are currently working, training, or have previous work experience in the NICU or pediatric wards at Shizuoka Saiseikai General Hospital, which admits approximately 300 newborns to the NICU annually, with around 100 newborns receiving mechanical ventilation. Written informed consent was obtained from all participants.

2.1. Devices Used

Two types of supraglottic airway devices were used, i-gel size 1 and laryngeal mask (standard laryngeal mask, Solus, Intersurgical Ltd., Wokingham, Berkshire, UK) size 1. For neonatal simulation manikins, the Neonatal Resuscitation Model LM-089 (Koken Co., Ltd., Bunkyo-ku, Tokyo, Japan) and Laerdal Neonatal Intubation Trainer (Laerdal Medical., Stavanger, Norway) were used (Figure 1).

2.2. Study Procedures

First, the participants were provided with the study procedures and instructed on how to use the laryngeal mask and the i-gel using printed instructions (Figure 1). Subsequently, a member of the study team, who was a qualified instructor in the neonatal cardiopulmonary resuscitation (NCPR) training course [16], demonstrated the insertion of each supraglottic airway device into both manikins. The water-soluble lubrication was used as instructed for each supraglottic airway device. All participants performed four insertion attempts using both types of supraglottic airway devices and manikins (Figure 1), the order of which was randomized using the RAND function of the spreadsheet software (Microsoft Excel 2013, Microsoft Corporation, Redmond, WA, USA). Two staff members observed each insertion attempt. The participants were instructed to declare the commencement of the insertion procedure, pick up the supraglottic airway device, and inform the staff when their attempts at insertion were complete. The time spent from the commencement of the procedure to its completion was recorded by a staff member of the study team. The study staff then connected the supraglottic airway device to a bag valve mask (Twenty-One Manual Resuscitator, Infants, GM Medical, Fukuoka, Japan) and manually ventilated it at a rate of approximately 60 times/min, according to the NCPR textbook [16]. When the bronchial pressure indicated on the built-in manometer showed elevations higher than $20 \text{ cmH}_2\text{O}$ more than six times in 10 ventilations, the attempt was considered successful. A video camera was used to record the procedure, along with the view of the manometer gauge, enabling video review in cases where the live assessment of the insertion time and success was ambiguous.

Children 2024, 11, 530 4 of 11

2.3. Backgrounds of Participants

We collected the background information of each participant, including specialty, years of healthcare service, previous experience using either type of neonatal supraglottic airway device, and past participation in an NCPR training course.

2.4. Data Analysis

All statistical analyses were performed using SPSS for Windows (ver. 29, IBM, Armonk, NY, USA). The primary outcome was the successful insertion of the supraglottic airway devices within an insertion time shorter than the 75th percentile of all successful attempts. The secondary outcomes were: (i) successful insertion regardless of the time spent, (ii) insertion time in all successful attempts, and (iii) successful insertion within an insertion time shorter than the 50th percentile of all successful attempts. A generalized estimating equation was used to investigate the dependence of outcomes on participants' backgrounds by incorporating findings from repeated assessments of the same participants. Logistic regression and linear regression structures were used for the binary and continuous outcomes, respectively. A univariate analysis was performed to determine the crude effect of each independent variable. For the primary outcome, multivariate analysis was performed to clarify the dependence of successful insertion on the supraglottic airway device type, with adjustment for the specialty, career, and experience of the participants and the order of insertion. The threshold for significance was set at p < 0.05 and not corrected for multiple comparisons; however, p-values close to the threshold were interpreted cautiously. Values are shown as number (percentage), mean (standard deviation), median (quartile ranges), odds ratio (OR), and 95% confidence intervals unless otherwise noted.

3. Results

3.1. Study Population

Ninety-one nurses (n = 41), midwives (n = 15), physicians (n = 15), student nurses (n = 13), medical clerks (n = 6), and one hospital specialist participated in the study. Forty-two (46%) participants completed the NCPR training course. The number of years of healthcare service was 5 (2–11) (Table 1).

Table 1. Backgrounds of participating providers.

Specialty *	
Nurse	41 (45.1)
Midwife	15 (16.5)
Physician	15 (16.5)
Student nurse	13 (14.3)
Medical clerk	6 (6.6)
Hospital play specialist	1 (1.1)
Experience and training *	
Years of healthcare service	5 (2–11)
Participation to NCPR course	168 (46.2)
Experience of using supraglottic airway devices	
i-gel	20 (5.5)
Laryngeal mask	36 (9.9)
Any of above	40 (11.0)
Outcomes **	
Time spent in s	
All attempts	11 (6–16)
Successful insertion only	11 (1–82)
Successful insertion	
Any success	200 (54.9)
Success < 16.7 s	149 (40.9)
Success < 10.9 s	97 (26.6)
Success < 6.5 s	45 (12.4)

Values are from * 91 providers and ** 364 insertion attempts, shown as number (%) or median (quartile range). Abbreviation: NCPR, Neonatal Cardio-Pulmonary Resuscitation.

Children **2024**, 11, 530 5 of 11

3.2. Total Successful Rate and Insertion Time

All participants successfully completed the study procedure, leaving data from 364 attempts available for analysis; no data were missing. Of the 364 insertion attempts made by the 91 participants, 200 (54.9%) were successful. The insertion time was 6.0 (10.7–16.4) s in the whole dataset and 6.5 (10.9–16.7) s when failed attempts were excluded.

3.3. Determinants of the Primary Outcome

In the univariate analysis, successful insertion < 16.4 s (75th percentile of all successful attempts) was negatively associated with the use of the Laerdal simulator (odds ratio [OR], 0.043; 05% 95% confidence interval [CI], 0.023–0.079; p < 0.001) and laryngeal mask (OR, 0.619; 95% CI, 0.464–0.825; p = 0.001) (Table 2).

Table 2. Determinants of successful insertion within 16.7 s (univariable analysis).

	Success < 16.7 s			Odds Ratio		
** • • •	Yes No		3.6	95% Confidence Interval		p
Variables	(n = 149)	(n = 215)	Mean	Lower	Upper	
Insertion order						
First	42 (46.2%)	49 (53.8%)		Reference		
Second	40 (44.0%)	51 (56.0%)	0.915	0.521	1.608	0.758
Third	36 (39.6%)	55 (60.4%)	0.764	0.426	1.369	0.365
Fourth	31 (34.1%)	60 (65.9%)	0.603	0.309	1.175	0.137
Specialty						
Physician	24 (40.0%)	36 (60.0%)	0.955	0.619	1.471	0.834
Other	125 (41.1%)	179 (58.9%)		Reference		
Years of healthcare se	rvice					
≤2	36 (39.1%)	56 (60.9%)	1.023	0.656	1.595	0.920
2–11	71 (38.6%)	113 (61.4%)		Reference		
>11	42 (47.7%)	46 (52.2%)	1.453	0.931	2.267	0.100
Participation to Neon	atal Cardio-Pulmon	ary Resuscitation co	urse			
Yes	70 (41.7%)	98 (58.3%)	1.058	0.724	1.546	0.771
No	79 (40.3%)	117 (60.0%)		Reference		
Experience of using i-	-gel	, ,				
Yes	8 (40.0%)	12 (60.0%)	0.96	0.588	1.566	0.870
No	141 (41.0%)	203 (59.0%)		Reference		
Experience of using la	aryngeal mask	, ,				
Yes	15 (41.7%)	21 (58.3%)	1.034	0.532	2.009	0.921
No	134 (40.9%)	194 (59.1%)		Reference		
Experience of using i-	gel or laryngeal ma	sk				
Yes	17 (42.5%)	23 (57.5%)	1.075	0.587	1.969	0.815
No	132 (40.7%)	192 (59.3%)		Reference		
Simulation manikin						
Laerdal	18 (9.9%)	164 (90.1%)	0.043	0.023	0.079	< 0.001
Koken	131 (72.0%)	51 (28.0%)		Reference		
Type of supraglottic a		• •				
Laryngeal mask	64 (35.2%)	118 (64.8%)	0.619	0.464	0.825	0.001
i-gel	85 (46.7%)	97 (53.3%)		Reference		

In the multivariate analysis adjusted for insertion order, occupation, and clinical experience, the outcome was negatively associated with the use of the Laerdal simulator (OR, 0.034; 05% 95% CI, 0.018–0.066; p < 0.001) and laryngeal masks (OR, 0.474; 95% CI, 0.292–0.771; p = 0.003) (Table 3).

Children **2024**, 11, 530 6 of 11

Table 3. Determinants of successful insertion within 16.7 s (multivariable analysis).

		Odds Ratio		
*7 ' 11	Maria	95% Confid	lence Interval	p
Variables	Mean	Lower	Upper	
Insertion order				
First		Refer	ence	
Second	0.625	0.287	1.359	0.236
Third	0.545	0.258	1.151	0.112
Fourth	0.434	0.192	0.982	0.045
Specialty				
Physician (vs. Othres)	0.843	0.24	2.963	0.790
Years of healthcare service				
≤2	1.065	0.458	2.475	0.884
2–11		Refer	ence	
>11	2.003	0.908	4.418	0.085
Experience of using supraglottic air	rway device			
Yes (vs. No)	1.312	0.283	6.08	0.728
Simulation manikin				
Laerdal (vs. Koken)	0.034	0.018	0.066	< 0.001
Type of supraglottic airway device				
Laryngeal mask (vs. i-gel)	0.474	0.292	0.771	0.003

3.4. Determinants of Secondary Outcomes

When the time spent on insertion was ignored, successful insertion was negatively associated with the use of the Laerdal simulator (OR, 0.004; 95% CI, 0.002–0.011; p < 0.001) (Table 4).

Table 4. Determinants of successful insertion (univariable analysis).

			Odds Ratio			
Variables	Yes (n = 200)	No (n = 164)	Mean	95% Confidence Lower	Interval Upper	p
Insertion order						
First	52 (57.1%)	39 (42.9%)		Reference		
Second	53 (58.2%)	38 (41.8%)	1.046	0.557	1.964	0.889
Third	50 (54.9%)	41 (45.0%)	0.915	0.493	1.697	0.777
Fourth	45 (49.5%)	46 (50.5%)	0.734	0.377	1.428	0.362
Specialty	, ,	, ,				
Physician	30 (50.0%)	30 (50.0%)	0.788	0.624	0.995	0.046
Other	170 (55.9%)	134 (44.1%)		Reference		
Years of healthcare servi	ce	, ,				
\leq 2	49 (53.3%)	43 (46.7%)	0.896	0.677	1.187	0.444
2–11	103 (56.0%)	81 (44.0%)		Reference		
>11	48 (54.5%)	40 (45.5%)	0.944	0.682	1.306	0.726
Participation to NCPR co	ourse	, ,				
Yes	92 (54.8%)	76 (45.2%)	0.986	0.77	1.264	0.913
No	108 (55.1%)	88 (44.9%)		Reference		
Experience of using i-gel	1					
Yes	10 (50.0%)	10 (50.0%)	0.811	0.711	0.924	0.002
No	190 (55.2%)	154 (44.8%)		Reference		
Experience of using lary	ngeal mask					
Yes	21 (58.3%)	15 (41.7%)	1.165	0.731	1.857	0.520
No	179 (54.6%)	149 (45.4%)		Reference		
Experience of using i-gel						
Ŷes	23 (57.5%)	17 (42.5%)	1.124	0.734	1.721	0.592
No	177 (54.6%)	147 (45.4%)		Reference		
Simulation manikin						
Laerdal	23 (12.6%)	159 (87.4%)	0.004	0.002	0.011	< 0.001
Koken	177 (97.3%)	5 (2.7%)		Reference		
Type of supraglottic airv						
Laryngeal mask	99 (54.4%)	83 (45.6%)	0.957	0.788	1.162	0.655
i-gel	101 (55.5%)	81 (44.5%)		Reference		

Children **2024**, 11, 530 7 of 11

When data from all successful attempts were assessed, the insertion time was associated with the duration of clinical experience (>11 years vs. 2–11 years; regression coefficient, 0.020; 95% CI, 0.001–0.602; p = 0.024) and the use of laryngeal masks (regression coefficient, 151.091; 95% CI, 11.099–2056.846; p < 0.001) (Table 5).

Table 5. Determinants of time spent for successful insertion (univariable analysis).

	Time (s)		Regression Coefficient	
Variables	Mean (Standard Deviation)	Mean	95% Confidence Interva	p
variables	Mean (Standard Deviation)	Mean	Lower Uppe	er
Insertion order				
First	12.4 (13.3)		Reference	
Second	14.8 (11.8)	2.448	-2.232 7.129	0.305
Third	14.2 (11.1)	1.821	-3.012 6.654	0.46
Fourth	13.3 (9.0)	0.897	-3.475 5.27	0.687
Specialty	` ,			
Physician	13.2 (13.8)	-0.645	-6.159 4.869	0.819
Other	13.8 (11.0)		Reference	
Years of healthcare service				
≤2	13.4 (13.6)	-1.64	-6.481 3.201	0.507
	15.0 (11.5)		Reference	
>11	11.1 (8.3)	-3.918	-7.329 -0.50	0.024
Participation to Neonatal (Cardio-Pulmonary Resuscitation cou	ırse		
Yes	13.5 (10.6)	-0.461	-3.926 3.004	0.794
No	13.9 (12.1)		Reference	
Experience of using i-gel	, ,			
Yes	12.9 (3.9)	-0.855	-4.133 2.423	0.609
No	13.7 (11.7)		Reference	
Experience of using laryng	• • • • • • • • • • • • • • • • • • • •			
Yes	13.0 (9.8)	-0.746	-5.236 3.745	0.745
No	13.8 (11.6)		Reference	
Experience of using i-gel of	* *			
Yes	13.0 (9.3)	-0.823	-5.005 3.359	0.700
No	13.8 (11.7)		Reference	
Simulation manikin	()			
Laerdal	11.0 (7.1)	-3.092	-6.584 0.400	0.083
Koken	14.1 (11.8)		Reference	
Type of supraglottic airwa				
Laryngeal mask	16.2 (8.5)	5.018	2.407 7.629	< 0.001
i-gel	11.2 (13.3)	2.2.2	Reference	

Successful insertion within 10.9 s (50th percentile of all successful attempts) was inversely associated with the Laerdal simulator (OR, 0.099; 95% CI, 0.054–0.182; p < 0.001) and laryngeal mask (OR, 0.196; 95% CI, 0.122–0.316; p < 0.001).

4. Discussion

Using two neonatal simulation manikins with different difficulties for supraglottic airway device insertion, we demonstrated that the i-gel was superior to the laryngeal mask, with a higher success rate within a fixed period and shorter insertion time among all successful attempts. The success rate was not associated with healthcare specialty, years of healthcare service, previous experience using supraglottic airway devices, or participation in NCPR training. These data suggest the potential advantages of using the i-gel and may justify the relevance of conducting a randomized trial comparing laryngeal masks and i-gels in neonatal resuscitation.

4.1. Comparison of Supraglottic Airway Devices in Airway Management

Since the first supraglottic airway device was proposed [6], several revised models have been created [7]. These newly developed devices are classified into those with air-

Children 2024, 11, 530 8 of 11

inflatable cuffs and those with ergonomically preshaped cuffs. The i-gel is a relatively new and unique supraglottic airway device with a gel-filled cuff. Findings from studies comparing insertion times between these devices lack consistency. Lee et al. compared the laryngeal mask (Laryngeal Mask Classic, Laryngeal Mask Company Ltd., Henleyon-Thames, UK) and i-gel in 99 children aged 1-108 months and demonstrated that the insertion time was shorter with the i-gel than with the laryngeal mask [8]. Kayhan et al. reported similar findings in favor of i-gel versus laryngeal masks (Laryngeal Mask ProSeal, LMA North America Inc., San Diego, CA, USA) in 50 infants weighing 2–5 kg [10]. However, a randomized equivalence trial in 170 children aged 3 months to 11 years showed no difference in the insertion time between the laryngeal mask (Laryngeal Mask Supreme, LMA North America, San Diego, CA, USA) and the i-gel [9]. Another randomized study in 54 relatively smaller infants weighing <10 kg also noted no difference in the insertion time between the laryngeal mask (classic laryngeal mask) and i-gel [11]. In contrast, a study of 60 randomized pediatric patients weighing between 10 and 25 kg found that the insertion time for the laryngeal mask (Laryngeal Mask Supreme) was significantly shorter than that of the i-gel [12]. These studies investigated the performance of supraglottic airway devices using a wide age range of children during the induction of general anesthesia. However, few studies have focused on airway management during neonatal resuscitation. Using neonatal simulation manikins, our study demonstrated that using the i-gel was associated with more precise and faster airway management than the laryngeal mask, regardless of the specialty and experience of the participating healthcare providers. These findings may justify the need for a randomized clinical trial to compare the performances of laryngeal masks and i-gels in neonatal resuscitation.

4.2. Dependence of Successful Insertion on Providers' Backgrounds

Thus far, few studies have investigated the dependence of successful supraglottic airway device insertion on the type of providers, presumably because most previous studies addressed supraglottic airway device-based airway management during general anesthesia, which is usually performed by trained anesthesiologists [8–15]. One study compared the success rates of airway management by nurse specialists, paramedics, and anesthesia residents using three different supraglottic airway devices in a neonatal simulation manikin (Ambu M-Mega Code Baby, Ambu, Hessen, Germany) [17]. This study found no significant differences in the success rates or airway management scores among the three health occupations. Our current study showed that the primary and secondary outcomes were not associated with specialty, years of healthcare service, previous experience using supraglottic airway devices, or participation in NCPR training, except that a longer duration of healthcare service showed a modest association with a shorter time to successful insertion. Our findings suggest that airway management using a laryngeal mask and i-gel is minimally influenced by the provider's background. The printed instructions and live demonstrations by the study team staff might have been sufficient to saturate the working image of the providers required to use these supraglottic airway devices. Indeed, in studies examining the efficacy of laryngeal masks in neonatal resuscitation, only a simple additional module was used in basic and essential newborn resuscitation programs [4,18]. However, another explanation is possible. In this study, as well as with previous experience of using supraglottic airway devices and participation in the NCPR course, the order of attempts did not affect the success rate of the insertion. Furthermore, we observed a trend of decreasing success rate with an increasing number of attempts. Although the exact reason remains unclear, this may be explained by fatigue and loss of concentration resulting from multiple insertions. Airway management skills using supraglottic airway devices may be difficult to improve at a certain level. Training programs that provide extended skills for supraglottic airway device insertion are required.

Children 2024, 11, 530 9 of 11

4.3. Relevance of Evaluating Supraglottic Airway Devices in Simulation Manikins

This study was conducted in neonatal simulation manikins. Owing to this setting, participating providers were able to repeat insertion attempts several times, which helped highlight the dependence of successful insertion on the device type and provider's backgrounds. To account for possible inter-neonate variations in the anatomical structure in the clinical setting, we used two different types of neonatal simulation manikins. While both manikins were designed to mimic term neonates weighing 2.5-3.5 kg and are widely used in Japanese NCPR training courses, the success rate of insertion remained at 9.9% for the Laerdal model and 72.0% for the Koken model. Several settings specific to the current study might have contributed to the relatively low success rate. First, since the Laerdal manikin is specifically designed for endotracheal intubation training, the tongue is relatively larger in size, leaving less space around the larynx compared to the Koken manikin (Figure 1). Thus, structural issues might have contributed to the lower insertion success rate, especially for the Laerdal manikin. Second, the participating providers were given only a brief instruction and demonstration before performing airway management, which might be improved with a number of appropriate practice sessions using the same devices. Third, although we used lubrication before insertion, its efficacy might differ between two SGA devices, and also between manikins and human neonates. Finally, we defined successful insertion as achieving the peak pressure of \geq 20 cmH₂O with a constant squeezing force of the bag provided by an experienced staff neonatologist. However, in clinical settings, the squeezing force can be adjusted in response to poor chest movement until sufficient ventilation is achieved. Therefore, the current definition of successful insertion might excessively be stringent, presumably identifying highly precise insertions of SGA devices with the minimum leakage of the air. Indeed, in a study using a neonatal manikin, failures in insertion attempt and airway management were defined as removal of the device from the mouth and a failure to achieve a successful insertion within the three attempts, respectively [19]. Another study using seven different SGA devices and a self-inflating bag in a neonatal manikin demonstrated that the mean peak inspiratory pressure of 20 cmH₂O was achieved with only three devices [20]. As Micaglio et al. performed in their study of a neonatal manikin, different positive pressures may need to be applied in future studies to compare the level of oropharyngeal leak pressures between different SGA devices [21]. These fundamental differences between resuscitation simulating in future clinical studies are required to assess these findings in simulation manikins and human neonates need to be noted when interpreting our findings into clinical practice.

4.4. Limitaions

In addition to the significant difference between resuscitation manikins and human neonates, several other limitations of our study need to be considered. First, unlike most previous studies that targeted a relatively wide range of infants and children undergoing general anesthesia, our study focused on neonatal resuscitation. Subsequently, only size 1.0 laryngeal mask and i-gel were used with neonatal resuscitation manikins, rendering comparisons with other studies difficult. Considering the increasing use of supraglottic airway devices in preterm infants, including those as young as 28 weeks gestational age and with birth weights as low as 810 g [22], further research using manikins designed to mimic preterm-born neonates is warranted. Second, this study recruited providers at a single center, resulting in relatively uniform backgrounds of the participating providers, especially in terms of their skills in neonatal resuscitation. Additionally, because of the limited study population, we were not able to fully assess the influence of providers' backgrounds to the outcome.

5. Conclusions

Our study of 91 healthcare providers suggested that for the airway management of neonatal simulator manikins, using i-gel was associated with a higher success rate within a fixed time and shorter insertion time within successful attempts than that of the laryngeal Children **2024**, 11, 530

mask. Considering that the provider's specialty, experience, and training had minimal impact on successful insertion, prospective clinical studies are warranted to investigate the potential advantage of using the i-gel for neonatal resuscitation by comparing laryngeal masks and i-gels.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/children11050530/s1, Figure S1: Instruction for LMA; Figure S2: Instruction for i-gel.

Author Contributions: Conceptualization, T.S. (Takahiro Sugiura), R.U. and O.I.; Data curation, R.U., S.F., T.S. (Tsutomu Shioda) and O.I.; Formal analysis, T.S. (Takahiro Sugiura), R.U., T.S. (Tsutomu Shioda) and O.I.; Funding acquisition, T.S. (Takahiro Sugiura) and O.I.; Investigation, T.S. (Takahiro Sugiura), R.U., T.S. (Tsutomu Shioda) and T.F.; Methodology, T.S. (Takahiro Sugiura), S.F., T.S. (Tsutomu Shioda) and O.I.; Project administration, T.S. (Takahiro Sugiura); Resources, T.S. (Takahiro Sugiura); Software, O.I.; Supervision, T.F. and O.I.; Validation, T.S. (Takahiro Sugiura), R.U. and T.S. (Tsutomu Shioda); Writing—original draft, T.S. (Takahiro Sugiura) and R.U.; Writing—review and editing, T.S. (Takahiro Sugiura), R.U., S.F., T.S. (Tsutomu Shioda), T.F. and O.I. All authors have read and agreed to the published version of the manuscript.

Funding: This study was supported by grants from the Ministry of Health, Labour, and Welfare of Japan (H24-Shinnkin-Ippan-001) and Japan Science and Technology Agency (COI-NEXT Program, JPMJPF2217).

Institutional Review Board Statement: The study protocol was approved by the Institutional Review Board of the Shizuoka Saiseikai General Hospital, Shizuoka, Japan (reference number: 20231601 on 4 March 2024).

Informed Consent Statement: Written informed consent was implied by the return of questionnaires sent to the participants who inquired about their background information.

Data Availability Statement: The data presented in this study are available on request from the corresponding author due to privacy restrictions and ethical reasons.

Acknowledgments: The authors thank all study participants.

Conflicts of Interest: The authors declare no conflicts of interest.

References

- 1. Wyckoff, M.H.; Wyllie, J.; Aziz, K.; de Almeida, M.F.; Fabres, J.; Fawke, J.; Guinsburg, R.; Hosono, S.; Isayama, T.; Kapadia, V.S.; et al. Neonatal Life Support: 2020 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. *Circulation* 2020, 142 (Suppl. S1), S185–S221. [CrossRef] [PubMed]
- 2. Ersdal, H.L.; Mduma, E.; Svensen, E.; Perlman, J.M. Early initiation of basic resuscitation interventions including face mask ventilation may reduce birth asphyxia related mortality in low-income countries: A prospective descriptive observational study. *Resuscitation* **2012**, *83*, 869–873. [CrossRef] [PubMed]
- 3. Foglia, E.E.; Ades, A.; Sawyer, T.; Glass, K.M.; Singh, N.; Jung, P.; Quek, B.H.; Johnston, L.C.; Barry, J.; Zenge, J.; et al. Neonatal Intubation Practice and Outcomes: An International Registry Study. *Pediatrics* **2019**, *143*, e20180902. [CrossRef] [PubMed]
- 4. Pejovic, N.J.; Trevisanuto, D.; Lubulwa, C.; Myrnerts Hook, S.; Cavallin, F.; Byamugisha, J.; Nankunda, J.; Tylleskär, T. Neonatal resuscitation using a laryngeal mask airway: A randomised trial in Uganda. *Arch. Dis. Child.* **2018**, *103*, 255–260. [CrossRef]
- 5. Wyckoff, M.H.; Greif, R.; Morley, P.T.; Ng, K.C.; Olasveengen, T.M.; Singletary, E.M.; Soar, J.; Cheng, A.; Drennan, I.R.; Liley, H.G.; et al. 2022 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations: Summary From the Basic Life Support; Advanced Life Support; Pediatric Life Support; Neonatal Life Support; Education, Implementation, and Teams; and First Aid Task Forces. *Circulation* 2022, 146, e483–e557.
- 6. Brain, A.I. The laryngeal mask—A new concept in airway management. *Br. J. Anaesth.* 1983, 55, 801–805. [CrossRef] [PubMed]
- 7. van Zundert, T.C.; Brimacombe, J.R.; Ferson, D.Z.; Bacon, D.R.; Wilkinson, D.J. Archie Brain: Celebrating 30 years of development in laryngeal mask airways. *Anaesthesia* **2012**, *67*, 1375–1385. [CrossRef]
- 8. Lee, J.R.; Kim, M.S.; Kim, J.T.; Byon, H.J.; Park, Y.H.; Kim, H.S.; Kim, C.S. A randomised trial comparing the i-gel (TM) with the LMA Classic (TM) in children. *Anaesthesia* **2012**, *67*, 606–611. [CrossRef]
- 9. Jagannathan, N.; Sommers, K.; Sohn, L.E.; Sawardekar, A.; Shah, R.D.; Mukherji, I.I.; Miller, S.; Voronov, P.; Seraphin, S. A randomized equivalence trial comparing the i-gel and laryngeal mask airway Supreme in children. *Paediatr. Anaesth.* **2013**, 23, 127–133. [CrossRef]
- 10. Kayhan, G.E.; Begec, Z.; Sanli, M.; Gedik, E.; Durmus, M. Performance of size 1 I-gel compared with size 1 ProSeal laryngeal mask in anesthetized infants and neonates. *Sci. World J.* **2015**, 2015, 426186. [CrossRef]

Children **2024**, 11, 530

11. Kim, M.S.; Oh, J.T.; Min, J.Y.; Lee, K.H.; Lee, J.R. A randomised comparison of the i-gel and the Laryngeal Mask Airway Classic in infants. *Anaesthesia* **2014**, *69*, 362–367. [CrossRef] [PubMed]

- 12. Kus, A.; Gok, C.N.; Hosten, T.; Gurkan, Y.; Solak, M.; Toker, K. The LMA-Supreme versus the I-gel in simulated difficult airway in children: A randomised study. *Eur. J. Anaesthesiol.* **2014**, *31*, 280–284. [CrossRef] [PubMed]
- 13. Oba, S.; Turk, H.S.; Kilinc, L.; Eksioglu Karaci, B.; Islamoglu, S. Comparing I-Gel to Proseal Laryngeal Mask Airways in Infants: A Prospective Randomised Clinical Study. *Turk. J. Anaesthesiol. Reanim.* **2020**, *48*, 308–313. [CrossRef] [PubMed]
- 14. Sanket, B.; Ramavakoda, C.Y.; Nishtala, M.R.; Ravishankar, C.K.; Ganigara, A. Comparison of Second-Generation Supraglottic Airway Devices (i-gel versus LMA ProSeal) during Elective Surgery in Children. *AANA J.* **2015**, *83*, 275–280. [PubMed]
- 15. Theiler, L.G.; Kleine-Brueggeney, M.; Luepold, B.; Stucki, F.; Seiler, S.; Urwyler, N.; Greif, R. Performance of the pediatric-sized i-gel compared with the Ambu AuraOnce laryngeal mask in anesthetized and ventilated children. *Anesthesiology* **2011**, *115*, 102–110. [CrossRef] [PubMed]
- 16. The Text Book of NCPR. The Japan Society of Perinatal and Neonatal Medicine (JSPNM): Tokyo, Japan. Available online: http://www.ncpr.jp/eng/doc/Textbook_of_NCPR.pdf (accessed on 19 January 2024).
- 17. Ritzka, M.; Schunk, D.; Hopf, S.; Bitzinger, D.; Graf, B.; Trabold, B. A Comparison of Three Different Supraglottic Airway Devices in Neonatal Airway Training during Resuscitation Simulation. *Int. J. Anesth. Anesthesiol.* **2016**, *3*, 044. [CrossRef]
- 18. Pejovic, N.J.; Myrnerts Hook, S.; Byamugisha, J.; Alfven, T.; Lubulwa, C.; Cavallin, F.; Nankunda, J.; Ersdal, H.; Blennow, M.; Trevisanuto, D.; et al. A Randomized Trial of Laryngeal Mask Airway in Neonatal Resuscitation. *N. Engl. J. Med.* **2020**, *383*, 2138–2147. [CrossRef] [PubMed]
- 19. Trevisanuto, D.; Parotto, M.; Doglioni, N.; Ori, C.; Zanardo, V.; Micaglio, M. The Supreme Laryngeal Mask Airway™ (LMA): A new neonatal supraglottic device: Comparison with Classic and ProSeal LMA in a manikin. *Resuscitation* **2012**, *83*, 97–100. [CrossRef] [PubMed]
- 20. Tracy, M.B.; Priyadarshi, A.; Goel, D.; Lowe, K.; Huvanandana, J.; Hinder, M. How do different brands of size 1 laryngeal mask airway compare with face mask ventilation in a dedicated laryngeal mask airway teaching manikin? *Arch. Dis. Child. Fetal Neonatal Ed.* 2018, 103, F271–F276. [CrossRef]
- 21. Micaglio, M.; Trevisanuto, D.; Doglioni, N.; Zanette, G.; Zanardo, V.; Ori, C. The size 1 LMA-ProSeal: Comparison with the LMA-Classic during pressure controlled ventilation in a neonatal intubation manikin. *Resuscitation* **2007**, 72, 124–127. [CrossRef]
- 22. Gallup, J.A.; Ndakor, S.M.; Pezzano, C.; Pinheiro, J.M.B. Randomized Trial of Surfactant Therapy via Laryngeal Mask Airway versus Brief Tracheal Intubation in Neonates Born Preterm. *J. Pediatr.* **2023**, 254, 17–24.e2. [CrossRef] [PubMed]

Disclaimer/Publisher's Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.