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Manikin-based noninferiority simulation study of Airgency™: A novel automatic bag valve mask device for emergency respiratory support

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Abstract:

OBJECTIVES: This study evaluated the performance of Airgency™, an automated bag valve mask (BVM) ventilation device developed by Institut Teknologi Bandung and Padjadjaran University, Indonesia, using a manikin-based simulation model. Its performance was compared with conventional hand-squeezed bagvalvemask ventilation performed by medical professionals, with a focus on reducing operator-dependent variability and fatigue.

METHODS: A manikin-based simulation was conducted using an adult airway trainer connected to a lung simulator (ASL5000) set to mimic apneic respiratory failure with normal lung mechanics. The Ambu bag, connected to 15 L/min oxygen, was secured to the manikin. Airgency™ operated in normal mode (tidal volume [VT] 400 mL, 15 bpm) for 30 min, repeated 50 times. Seventy-eight anaesthesiology residents performed manual BVM ventilation under identical conditions after standardized training. Breathing rate (BR), VT, and peak inspiratory pressure (PIP) were recorded every minute, whereas fatigue was rated using the Visual Analog Scale for Fatigue (VAS-F, 1–10).

RESULTS: Airgency™ demonstrated superior ventilation stability. BR remained consistent (14.77 ± 0.08 vs. 16.54 ± 7.05 bpm; $P < 0.0001$), with much lower variability (coefficient of variation [CV] 0.47% vs. 46.1%–121.2%). VT delivery was steady (397.8 ± 3.1 vs. 406.9 ± 85.4 mL; $P < 0.0001$; CV 2.2% vs. 13.9%–25.7%), and PIP was more uniform (29.4 ± 0.9 vs. 23.1 ± 8.2 cmH₂O; $P < 0.00001$; CV 2.5% vs. 28.3%–41.1%). Operator fatigue increased progressively during manual ventilation (VAS-F 1.83–5.09; $P < 0.0001$).

CONCLUSION: Airgency™ maintained consistent, precise ventilation with minimal variability and eliminated operator fatigue, supporting its potential as a reliable alternative to manual BVM ventilation in emergency care.

Keywords:

Bag valve mask device, breathing rate, fatigue, peak inspiratory pressure, tidal volume

Introduction

Respiratory failure, a disruption in gas exchange, is a major cause of morbidity and mortality in intensive care, often leading

to hypoxemia and ventilatory failure.^[1] During pandemics, as seen in coronavirus disease-2019, ventilator shortages highlight the need for simple, affordable, and effective respiratory support.^[2]

The bag valve mask (BVM) is essential in emergencies for its portability and

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Box-ED Section**What is already known?**

- Bag valve mask (BVM) ventilation is essential for emergency respiratory support.

What is the conflict on the issue?

- Manual ventilation is prone to inconsistency and operator fatigue, increasing the risk of patient harm.
- Airgency™, an automated BVM device, was designed to address these issues, but evidence of its reliability in simulated emergencies is limited.

How is this study structured?

- A manikin-based simulation compared Airgency™ with manual BVM ventilation over 30 min.

What does this study tell us?

- Airgency™ provided more stable, consistent ventilation with minimal variability and no operator fatigue.

independence from power, serving as a bridge before advanced ventilation. However, performance depends on operator skill and endurance, with prolonged use risking complications such as gastric insufflation and pneumothorax.^[3,4]

To address these limitations, Airgency™, an automated BVM device developed by Institut Teknologi Bandung and Padjadjaran University, delivers consistent, controlled breaths while maintaining simplicity and portability.

A simulation-based evaluation is necessary before clinical application to assess the device's safety, reliability, and performance under standardized conditions. Using a manikin model allows objective comparison with trained medical personnel to evaluate ventilation consistency and reduce operator-dependent variability. This study, therefore, aims to assess the noninferiority of Airgency™ compared with manual BVM ventilation and its potential as a reliable alternative for emergency respiratory support.

Methods

Product details

Figure 1 shows the Airgency™ device, a compact 21 cm × 24 cm × 31 cm, 3 kg unit designed to provide assisted ventilation for adult patients with respiratory failure or cardiac arrest. To operate, the Ambu bag is secured between the presser arms, connected to the airflow sensor and power source (200–400 VAC, 50/60 Hz), and activated through the main switch. Airgency™ can also operate on its 5200 mAh battery for up to 2 h, with LEDs indicating green for external power and red for battery use.

The breathing parameters are adjustable with the following configurable settings:

- Tidal volume (VT): 300, 400, and 500 mL (fixed)
- Inspiration/Expiration (I/E) Ratio: 1:1, 1:2, and 1:3
- Breathing Rate: 10, 15, and 20 breath/min (fixed)
- Operating Mode: Normal and assisted mode.

The normal mode delivers preset ventilation for fully apneic patients, with system failure detected if three consecutive cycles are incomplete. The assisted mode aids patients with weak spontaneous breathing by synchronizing ventilation with inspiratory effort, minimizing over-assistance and breath-stacking. Failure is detected if no effort occurs within 10 s. LED indicators show mode status: green (normal), yellow (assisted), and red (failure).

The device was verified by the Center for Medical Device and Health Facility Safety, Ministry of Health, Republic of Indonesia (Approval No. YK.01.03/XLVIII.2/1346/2020, issued May 11, 2020), in compliance with the following standards: IEC 60601-1, IEC 60601-1-8, and ISO 80601-2-84 for safety and performance of ventilatory support equipment.

Ethical statement

This study was approved by the Research Ethics Committee of Padjadjaran University [Amendment No. 557/UN6. KEP/EC/2020]. Clinical trial registration was not required, as the study used a manikin-based simulation with medical professionals serving only as operators, and outcomes focused solely on device performance, not human health.

Sample size calculation

This study aimed to assess the noninferiority of Airgency™ compared to manual BVM ventilation by medical professionals. Sample size was calculated using a standard formula for comparing two groups with continuous outcomes:^[5]

$$n = \frac{2 (Z_{1-\alpha/2} + Z_{1-\beta})^2 s_p^2}{\Delta^2}$$

where:

n = required sample size per group

$Z_{1-\alpha/2}$ = standard normal deviate for desired confidence interval (CI) (1.96 for 95% CI)

$Z_{1-\beta}$ = standard normal deviate for desired power (0.84 for 80% power)

s_p = pooled groups standard deviation (SD)

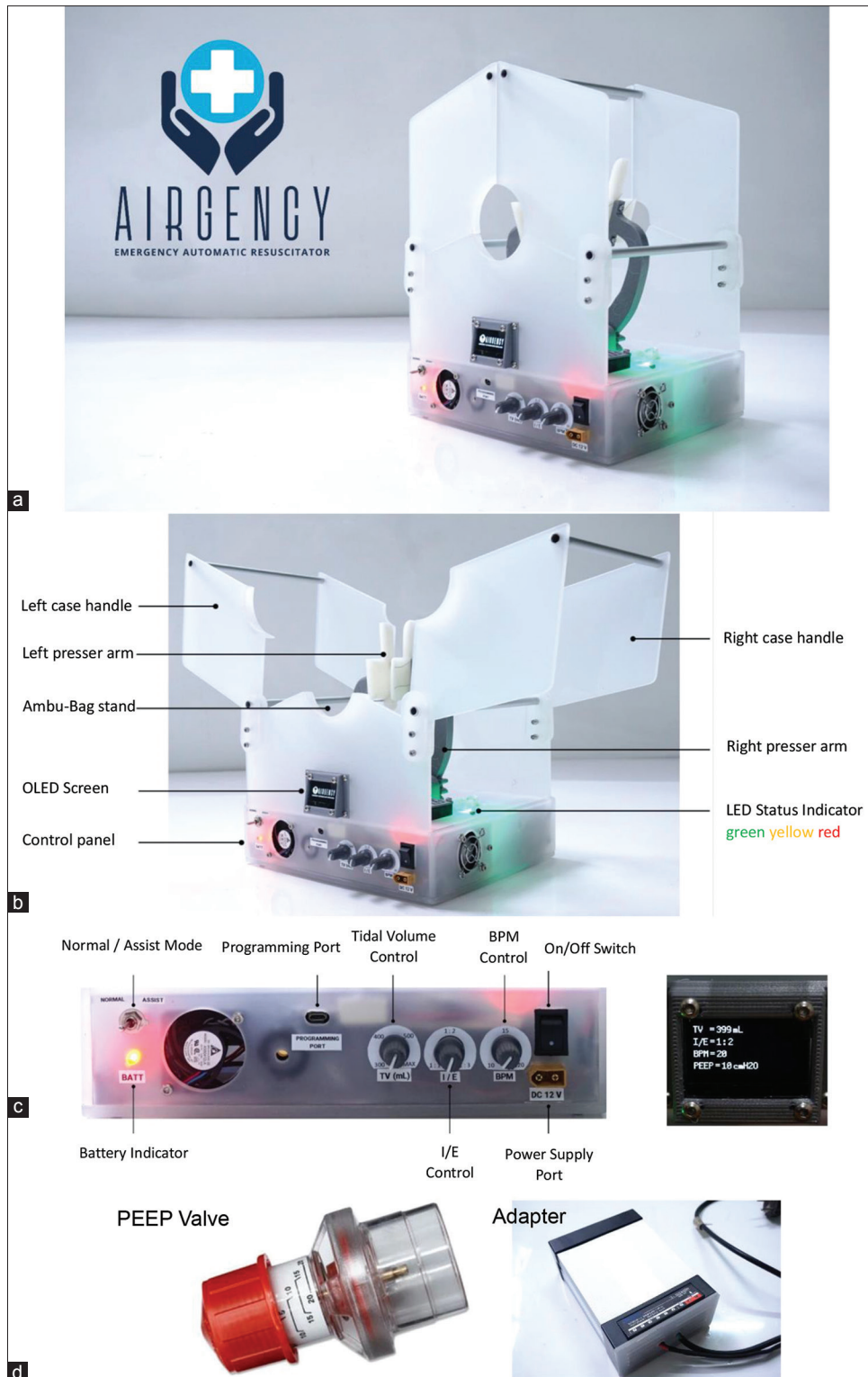


Figure 1: Design of Airgency™. (a) Closed form showing compact design, (b) Open form displaying internal layout, (c) Control panel with OLED screen, LED indicators (green, yellow, and red), ports, and control knobs (tidal volume, BPM, and I/E ratio), (d) Supporting components, including PEEP valve and adapter

Δ = noninferiority margin, the maximum clinically acceptable difference between groups.

The primary outcome for ventilation performance was the delivered VT; therefore, the mean difference (MD)

and SD of VT were used for sample size estimation. According to ISO 80601-2-84, the allowable deviation in delivered volume is $\pm 15\%$ of the set value. With a set VT of 400 mL, this corresponds to an allowable deviation of approximately 60 mL.

Previous studies reported SDs of 94 mL,^[4] 160.3 mL,^[6] and 164 mL^[7] for manual BVM ventilation, yielding an average SD of about 140 mL. In contrast, bench testing of Airgency™ demonstrated an SD of 16–20 mL. The pooled SD (s_p) was then calculated using the following formula:

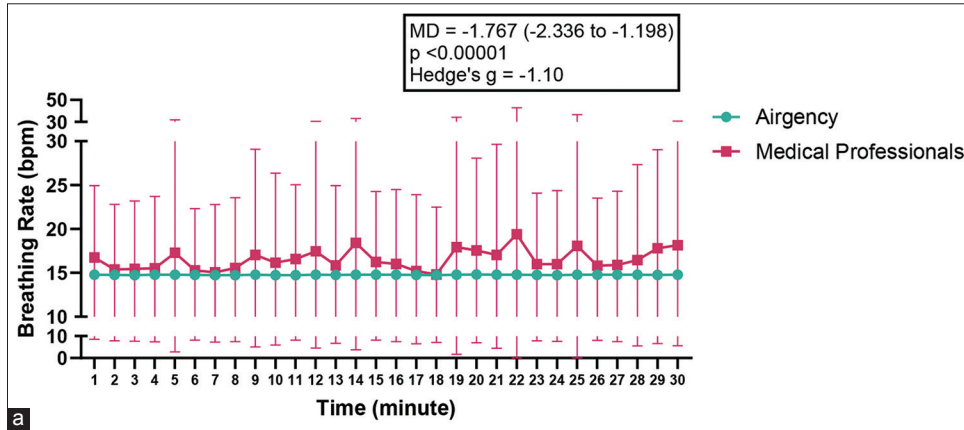
$$S_p = \sqrt{\frac{S_1^2 + S_2^2}{2}}$$

where:

s_1 = SD of Airgency™

s_2 = SD of control group (manual BVM)

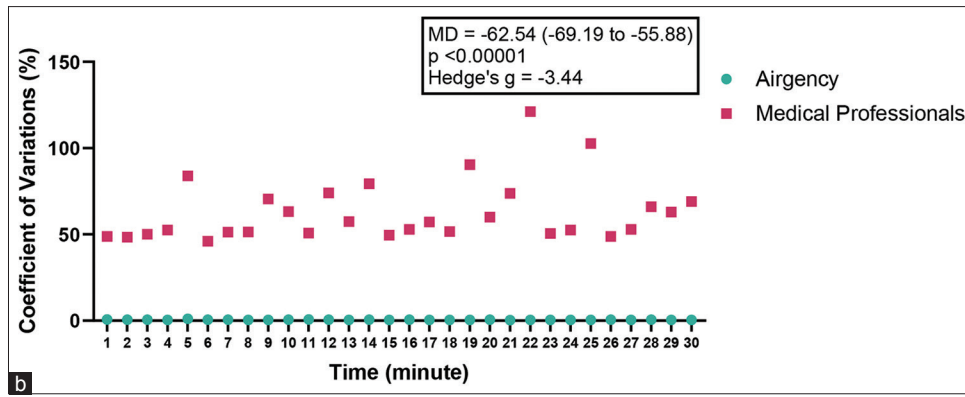
Using the previously derived values, the pooled SD (s_p) was estimated at 100 mL. Applying $s_p=100$ mL and a noninferiority margin (Δ) = 60 mL in the sample



	1	2	3	4	5	6	7	8	9	10
Mean airgency	14.78	14.76	14.75	14.8	14.8	14.77	14.75	14.74	14.78	14.75
SD airgency	0.1	0.09	0.07	0.07	0.16	0.08	0.09	0.06	0.06	0.08
Mean MP	16.76	15.37	15.46	15.54	17.29	15.28	15.06	15.55	17.04	16.16
SD MP	8.19	7.44	7.74	8.17	14.52	7.05	7.72	8.00	12.04	10.20
Mean difference	-1.98	-0.61	-0.71	-0.74	-2.49	-0.51	-0.31	-0.81	-2.26	-1.41
95% CI	-5.1 to 1.14	-3.73 to 2.51	-3.83 to 2.41	-3.86 to 2.38	-5.61 to 0.63	-3.63 to 2.61	-3.43 to 2.81	-3.93 to 2.31	-5.38 to 0.85	-4.53 to 1.71
P	0.213	0.701	0.654	0.643	0.117	0.750	0.846	0.610	0.155	0.375
Hedge's g	-0.306	-0.104	-0.116	-0.114	-0.217	-0.091	-0.050	-0.128	-0.238	-0.175
	11	12	13	14	15	16	17	18	19	20
Mean airgency	14.75	14.78	14.76	14.78	14.78	14.79	14.77	14.74	14.79	14.81
SD airgency	0.1	0.07	0.06	0.09	0.06	0.07	0.06	0.06	0.06	0.08
Mean MP	16.59	17.47	15.85	18.43	16.23	16.02	15.21	14.82	17.93	17.55
SD MP	8.44	12.93	9.10	14.62	8.05	8.48	8.70	7.66	16.22	10.53
Mean difference	-1.84	-2.69	-1.09	-3.65	-1.45	-1.23	-0.44	-0.08	-3.14	-2.74
95% CI	-4.96 to 1.28	-5.81 to 0.43	-4.21 to 2.03	-6.77 to -0.53	-4.57 to 1.67	-4.35 to 1.89	-3.56 to 2.68	-3.19 to 3.04	-6.25 to -0.02	-5.86 to 0.38
P	0.248	0.091	0.494	0.022	0.363	0.440	0.783	0.962	0.049	0.085
Hedge's g	-0.275	-0.263	-0.151	-0.316	-0.227	-0.183	-0.064	-0.012	-0.244	-0.329
	21	22	23	24	25	26	27	28	29	30
Mean airgency	14.8	14.8	14.76	14.75	14.79	14.78	14.78	14.79	14.76	14.78
SD airgency	0.05	0.06	0.07	0.06	0.05	0.07	0.06	0.07	0.06	0.06
Mean MP	17.06	19.39	15.99	15.98	18.06	15.81	15.89	16.47	17.82	18.16
SD MP	12.58	23.49	8.09	8.39	18.54	7.71	8.41	10.88	11.22	12.54
Mean difference	-2.26	-4.59	-1.23	-1.23	-3.28	-1.03	-1.11	-1.68	-3.06	-3.38
95% CI	-5.37 to 0.86	-7.71 to -1.47	-4.35 to 1.89	-4.35 to 1.89	-6.39 to -0.16	-4.15 to 2.09	-4.23 to 2.01	-4.8 to 1.44	-6.18 to 0.06	-6.5 to -0.26
P	0.156	0.004	0.440	0.439	0.040	0.517	0.485	0.292	0.055	0.034
Hedge's g	-0.227	-0.247	-0.192	-0.185	-0.223	-0.169	-0.167	-0.195	-0.345	-0.341

CI: Confidence interval, SD: Standard deviation, MD: Mean difference, MP: Medical Professionals

Figure 2: Breathing Rate (BR) during 30-min bag valve mask ventilation simulation. Data are shown as mean ± standard deviation (SD). Tables present minute-by-minute values for mean, SD, mean difference (MD), 95% confidence interval, P value, and Hedges' g. The box above each graph summarizes the overall MD, P value, and Hedges' g. (a) BR trends over 30 min



	1	2	3	4	5	6	7	8	9	10
CV Airgency	0.7	0.6	0.5	0.4	1.1	0.5	0.6	0.4	0.4	0.5
CV MP	48.85	48.43	50.07	52.57	83.97	46.12	51.28	51.47	70.62	63.13
Difference	-48.15	-47.83	-49.57	-52.17	-82.87	-45.62	-50.68	-51.07	-70.22	-62.63
	11	12	13	14	15	16	17	18	19	20
CV Airgency	0.7	0.5	0.4	0.5	0.4	0.5	0.4	0.4	0.4	0.5
CV MP	50.87	74.02	57.4	79.34	49.61	52.94	57.2	51.73	90.48	60
Difference	-50.17	-73.52	-57	-78.84	-49.21	-52.44	-56.8	-51.33	-90.08	-59.5
	21	22	23	24	25	26	27	28	29	30
CV Airgency	0.3	0.4	0.4	0.4	0.4	0.5	0.4	0.5	0.4	0.4
CV MP	73.76	121.16	50.59	52.53	102.65	48.77	52.93	66.07	62.95	69.06
Difference	-73.46	-120.76	-50.19	-52.13	-102.25	-48.27	-52.53	-65.57	-62.55	-68.66

CV: Coefficient of variation, MD: Mean difference, MP: Medical Professionals

Figure 2: Breathing Rate (BR) during 30-min bag valve mask ventilation simulation. Data are shown as mean ± standard deviation (SD). Tables present minute-by-minute values for mean, SD, mean difference (MD), 95% confidence interval, P value, and Hedges' g. The box above each graph summarizes the overall MD, P value, and Hedges' g. (b) Coefficient of variation of delivered BR

size formula yielded the following calculated sample size:

$$n = \frac{2(1.96 + 0.84)^2(100)^2}{(60)^2} = 43.56 \approx 44$$

participant per group

Considering a 10% dropout rate, the minimum number of participants required is 48. Therefore, a minimum of 50 participants will be recruited.

Experiment setting

Manikin simulation setting

An adult respiratory manikin (Laerdal Airway Management Trainer, Laerdal Medical, Stavanger, Norway) was connected to a lung simulator (ASL5000, IngMar Medical, Pittsburgh, PA, USA) to measure ventilation parameters under simulated respiratory failure without spontaneous breathing. The simulator was set as a passive model with a lung compliance of 70 mL/cmH₂O and airway resistance of 5 cmH₂O/L/s, representing normal adult lung mechanics.^[8] The internal lungs of the manikin were bypassed, and ventilation was routed directly to the test lung simulator using a 22-mm-diameter, 36-cm-long hose with a Y-connector. The Ambu bag, connected to an

oxygen cylinder at 15 L/min, was secured with a mask fixation band.

Airgency™ settings

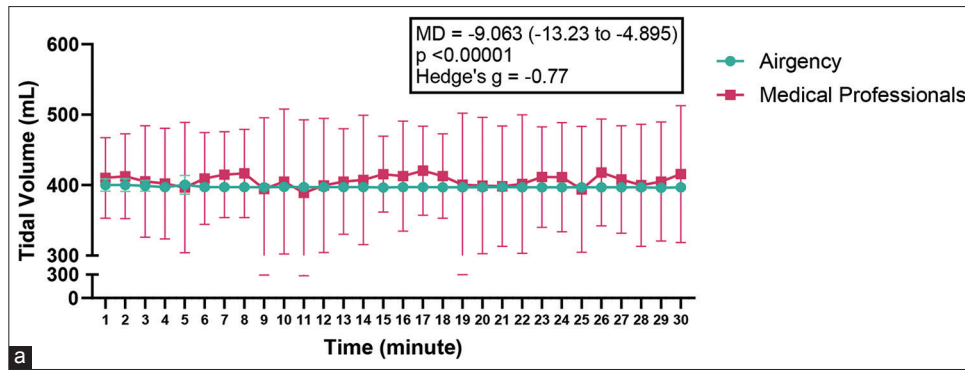
The Airgency™ device was configured to operate in normal mode, with a VT of 400 mL, I/E ratio 1:1, and a breathing rate (BR) of 15 breaths/min (bpm). The BVM ventilation procedure was done for 30 min and repeated 50 times.

Manual ventilation control group

Medical professionals were recruited based on the following criteria: (1) enrollment in the 1st-3rd year of anesthesiology and intensive care residency, (2) body mass index 18.5-24.9, (3) valid ALS certification, (4) ≥2 years of clinical experience, (5) good physical health, (6) rest day participation, and (7) ≥6 h of sleep before testing. Informed consent was obtained from all participants.

Before testing, participants received standardized instruction and brief hands-on training in BVM ventilation using the manikin setup, followed by a 1-min pretest to standardize rhythm and mask sealing.

Each participant then performed manual BVM ventilation for 30 min at a target rate of 15 breaths/min and VT of



	1	2	3	4	5	6	7	8	9	10
Mean Airgency	400.2	400.1	398.9	397.3	400.5	397.3	397.1	397.0	396.8	397.4
SD Airgency	8.8	8.9	7.5	3.3	13.2	3.3	3.0	2.5	2.6	2.8
Mean MP	410.2	412.6	405.2	402.1	396.6	409.4	414.9	416.6	394.3	405.0
SD MP	57.2	60.2	79.1	78.5	92.5	65.2	61.1	62.6	101.3	102.8
Mean difference	-10.04	-12.53	-6.33	-4.82	3.9	-12.1	-17.73	-19.56	2.45	-7.64
95% CI	-32.9 to 12.8	-35.4 to 10.3	-29.2 to 16.5	-27.7 to 18	-18.9 to 26.7	-34.9 to 10.7	-40.6 to 5.1	-42.4 to 3.3	-20.4 to 25.3	-30.5 to 15.2
<i>P</i>	0.389	0.282	0.587	0.679	0.738	0.299	0.128	0.093	0.834	0.512
Hedge's g	-0.220	-0.261	-0.101	-0.078	0.053	-0.234	-0.367	-0.395	0.031	-0.094
	11	12	13	14	15	16	17	18	19	20
Mean Airgency	397.2	397.2	397.2	397.2	396.5	397.2	397.1	396.8	396.9	396.9
SD Airgency	3.0	2.6	2.7	2.9	2.3	2.6	2.7	2.4	2.4	2.4
Mean MP	389.1	399.5	405.1	407.3	415.6	412.7	420.5	412.9	400.5	399.4
SD MP	103.5	95.3	75.0	91.8	53.9	78.0	63.2	59.9	101.7	96.8
Mean difference	8.08	-2.37	-7.9	-10.13	-19.11	-15.55	-23.45	-16.05	-3.63	-2.51
95% CI	-14.8 to 30.9	-25.2 to 20.5	-30.7 to 14.9	-33 to 12.7	-41.9 to 3.7	-38.4 to 7.3	-46.3 to -0.6	-38.9 to 6.8	-26.5 to 19.2	-25.3 to 20.3
<i>P</i>	0.488	0.839	0.497	0.385	0.101	0.182	0.044	0.168	0.756	0.829
Hedge's g	0.099	-0.031	-0.133	-0.139	-0.448	-0.252	-0.469	-0.339	-0.045	-0.033
	21	22	23	24	25	26	27	28	29	30
Mean Airgency	397.1	396.9	396.7	396.9	397.0	396.9	397.0	396.9	396.3	396.8
SD Airgency	2.4	2.5	2.3	2.3	2.0	2.5	2.5	2.5	2.3	2.6
Mean MP	398.4	401.6	411.5	411.3	394.0	418.0	408.0	399.8	405.1	415.7
SD MP	85.4	98.3	71.3	77.6	89.4	75.8	76.3	86.7	84.6	97.1
Mean difference	-1.37	-4.71	-14.76	-14.34	3.01	-21.1	-11.03	-2.95	-8.73	-18.9
95% CI	-24.2 to 21.5	-27.5 to 18.1	-37.6 to 8.1	-37.2 to 8.5	-19.8 to 25.8	-43.9 to 1.7	-33.9 to 11.8	-25.8 to 19.9	-31.6 to 14.1	-41.7 to 3.9
<i>P</i>	0.906	0.686	0.205	0.218	0.796	0.07	0.344	0.8	0.454	0.105
Hedge's g	-0.020	-0.061	-0.261	-0.233	0.043	-0.352	-0.183	-0.043	-0.130	-0.246

CI: Confidence interval, SD: Standard deviation, MD: Mean difference, MP: Medical Professionals

Figure 3: Tidal Volume (VT) during 30-min bag-valve-mask ventilation simulation. Data are shown as mean ± standard deviation (SD). Tables present minute-by-minute values for mean, SD, mean difference (MD), 95% confidence interval, *P* value, and Hedges' *g*. The box above each graph summarizes the overall MD, *P* value, and Hedges' *g*. (a) VT trends over 30 min

400 mL under standardized experimental conditions to ensure consistent comparison with the Airgency™ device.

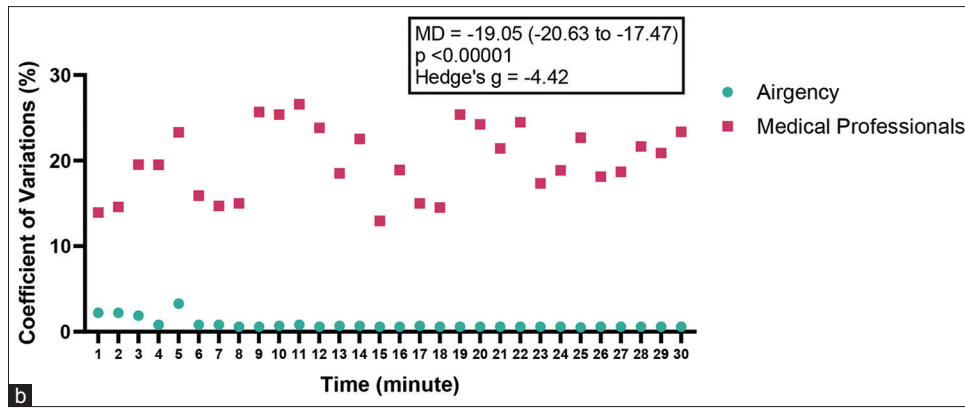
Outcome measure

BR, VT, and peak inspiratory pressure (PIP) were recorded every minute using integrated pressure and flow transducers of the lung simulator, with data logged in real time on a connected computer. A medical device engineer supervised all measurements during the 30-min simulation.

Operator fatigue was assessed using the Visual Analog Scale for Fatigue (VAS-F), ranging from 1 (no fatigue) to 10 (extreme fatigue). During manual BVM ventilation, participants verbally reported their fatigue score every minute. Responses were documented by a data collector on a case report form and later transcribed into a digital database for analysis.

Statistical analysis

All analyses were conducted using GraphPad Prism version 10.1.2 (GraphPad Software, 2023, San Diego, CA,



	1	2	3	4	5	6	7	8	9	10
CV Airgency	2.20	2.20	1.90	0.80	3.30	0.80	0.80	0.60	0.60	0.70
CV MP	13.94	14.60	19.53	19.51	23.32	15.92	14.72	15.02	25.69	25.39
Difference	-11.74	-12.40	-17.63	-18.71	-20.02	-15.12	-13.92	-14.42	-25.09	-24.69
	11	12	13	14	15	16	17	18	19	20
CV Airgency	0.80	0.60	0.70	0.70	0.60	0.60	0.70	0.60	0.60	0.60
CV MP	26.60	23.85	18.50	22.54	12.97	18.91	15.02	14.50	25.39	24.24
Difference	-25.80	-23.25	-17.80	-21.84	-12.37	-18.31	-14.32	-13.90	-24.79	-23.64
	21	22	23	24	25	26	27	28	29	30
CV Airgency	0.60	0.60	0.60	0.60	0.50	0.60	0.60	0.60	0.60	0.60
CV MP	21.43	24.49	17.34	18.87	22.68	18.14	18.70	21.67	20.89	23.37
Difference	-20.83	-23.89	-16.74	-18.27	-22.18	-17.54	-18.10	-21.07	-20.29	-22.77

CV: Coefficient of variation, MD: Mean difference, MP: Medical Professionals

Figure 3: Tidal Volume (VT) during 30-min bag-valve-mask ventilation simulation, Data are shown as mean ± standard deviation (SD). Tables present minute-by-minute values for mean, SD, mean difference (MD), 95% confidence interval, *P* value, and Hedges' *g*. The box above each graph summarizes the overall MD, *P* value, and Hedges' *g*. (b) Coefficient of variation of delivered VT

Table 1: Baseline characteristics of participating residents

Characteristics	Number of residents (n=78) (%)
Sex	
Male	56 (71.8)
Female	22 (28.2)
Age (years)	
Mean±SD	31.85±2.71
Median (range)	32.00 (30–39)
Years of residency	
1 st year	36 (46.2)
2 nd year	19 (24.4)
3 rd year	23 (29.4)
Clinical experience before entering residency (years)	
2–5	46 (58.9)
6–10	32 (41.1)

SD: Standard deviation

USA). Continuous data are presented as mean ± SD, with MDs, 95% CIs, and *P* values reported for key comparisons.

Because repeated minute-by-minute measurements were correlated, a mixed-effects model was applied to account for within-subject and within-run variability. Group (Airgency™ vs. manual) and time (minute) were treated as fixed effects, with their interaction used

to assess temporal trends. Random intercepts were included to account for baseline differences. *P* < 0.05 was considered statistically significant.

The standardized MD between groups was estimated using Hedges' *g*, with the following criterion:^[9]

- Small effect size (0.0–0.5)
- Medium effect size (0.5–0.8)
- Large effect size (0.8–1.4)
- Very large effect size (>1.4).

Results

Baseline characteristics of participating residents

A total of 78 anesthesiology and intensive care residents participated, exceeding the initial target of 50. Baseline characteristics are presented in Table 1. The male-to-female ratio was approximately 7:3, with most participants aged 32 years and in their 1st year of training (46.2%). Before residency, 58.9% had 2–5 years and 41.1% had 6–10 years of clinical experience.

Breathing rate, tidal volume, and peak inspiratory pressure

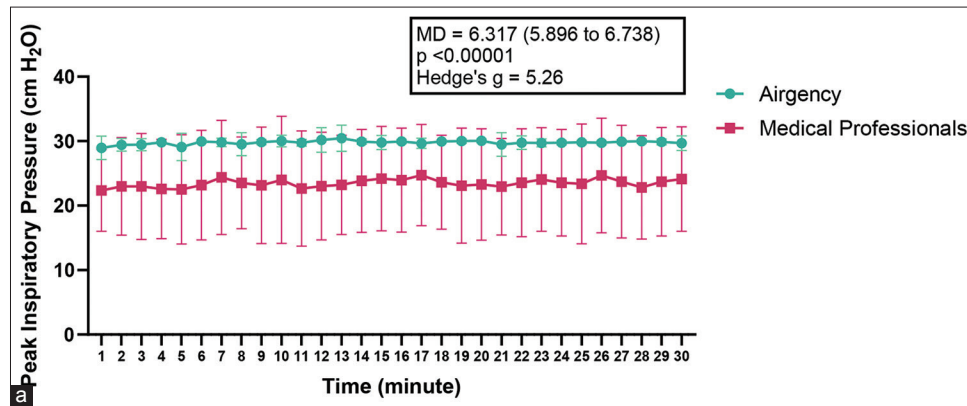
For BR, Airgency™ maintained stable performance (14.77 ± 0.08 bpm) with minimal variability, whereas

manual BVM showed greater fluctuation (16.54 ± 7.05 bpm). The MD was -1.77 bpm (95% CI -2.34 to -1.20 ; $P < 0.0001$; Hedges' $g = -1.10$) [Figure 2a]. Effect sizes per time point ranged from -0.10 to -0.31 , indicating small differences, and no significant time ($P = 0.9790$) or interaction effects ($P = 0.9844$) were found. The coefficient of variation (CV) was much lower with Airgency™ ($0.47\% \pm 0.07\%$) than with manual ventilation ($46.1\%–121.2\%$; $P < 0.0001$; $g = -3.44$) [Figure 2b].

For VT, Airgency™ maintained steady delivery (397.8 ± 3.1 mL) with minimal deviation, while manual

BVM showed greater variability (406.9 ± 85.4 mL). The MD was -9.06 mL (95% CI -13.23 to -4.90 ; $P < 0.0001$; $g = -0.77$). Effect sizes per time point (-0.020 to -0.395) indicated small differences [Figure 3a], with no significant time ($P = 0.9926$) or interaction effects ($P = 0.9906$). The CV was lower for Airgency™ ($2.20\% \pm 0.6\%$) versus manual ventilation ($13.9\%–25.7\%$; $P < 0.0001$; $g = -4.42$) [Figure 3b].

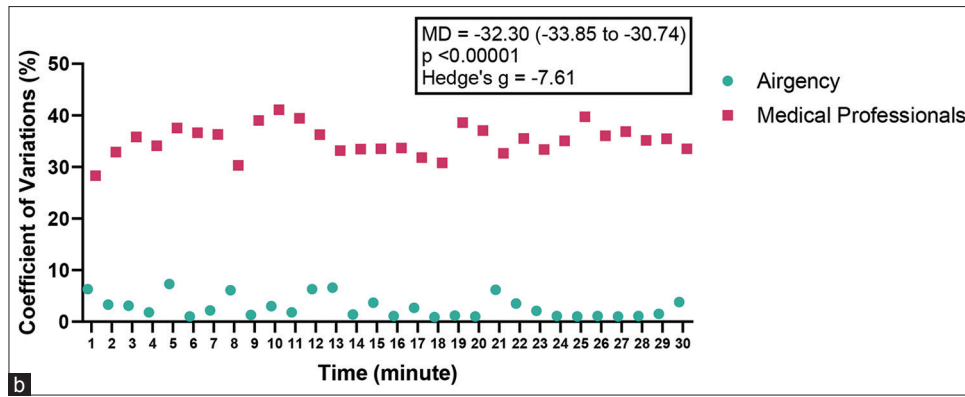
For PIP, Airgency™ achieved uniform pressure (29.4 ± 0.9 cmH₂O) compared to more variable manual ventilation (23.1 ± 8.2 cmH₂O). The MD was 6.32



	1	2	3	4	5	6	7	8	9	10
Mean Airgency	28.96	29.43	29.45	29.82	29.09	29.94	29.81	29.53	29.84	30.00
SD Airgency	1.82	0.97	0.92	0.55	2.12	0.29	0.65	1.79	0.40	0.90
Mean MP	22.35	22.97	22.97	22.59	22.53	23.20	24.38	23.53	23.15	23.99
SD MP	6.32	7.56	8.22	7.71	8.47	8.50	8.85	7.13	9.04	9.86
Mean difference	6.61	6.46	6.48	7.230	6.56	6.75	5.43	6	6.69	6.01
95% CI	4.3 to 8.92	4.15 to 8.76	4.17 to 8.79	4.92 to 9.53	4.25 to 8.87	4.44 to 9.05	3.13 to 7.74	3.69 to 8.31	4.39 to 9	3.7 to 8.32
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Hedge's g	1.29	1.07	0.99	1.18	0.96	1.00	0.77	1.04	0.94	0.77
	11	12	13	14	15	16	17	18	19	20
Mean Airgency	29.74	30.18	30.45	29.92	29.79	29.95	29.66	29.95	30.01	30.05
SD Airgency	0.53	1.90	2.02	0.42	1.10	0.33	0.79	0.28	0.35	0.31
Mean MP	22.65	23.03	23.22	23.84	24.17	23.94	24.73	23.63	23.09	23.29
SD MP	8.94	8.35	7.71	7.98	8.10	8.07	7.86	7.28	8.92	8.63
Mean difference	7.09	7.15	7.23	6.08	5.62	6.01	4.93	6.32	6.92	6.76
95% CI	4.78 to 9.4	4.85 to 9.46	4.92 to 9.54	3.77 to 8.38	3.31 to 7.92	3.71 to 8.32	2.62 to 7.24	4.01 to 8.63	4.61 to 9.22	4.45 to 9.07
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Hedge's g	1.00	1.06	1.16	0.96	0.87	0.94	0.79	1.10	0.98	0.99
	21	22	23	24	25	26	27	28	29	30
Mean Airgency	29.48	29.75	29.73	29.75	29.81	29.75	29.92	29.97	29.89	29.67
SD Airgency	1.83	1.05	0.63	0.34	0.29	0.33	0.29	0.33	0.46	1.13
Mean MP	22.94	23.56	24.06	23.55	23.37	24.67	23.72	22.82	23.71	24.12
SD MP	7.49	8.37	8.03	8.26	9.28	8.90	8.74	8.02	8.42	8.09
Mean difference	6.54	6.19	5.67	6.2	6.44	5.08	6.2	7.15	6.18	5.55
95% CI	4.23 to 8.84	3.89 to 8.5	3.36 to 7.98	3.89 to 8.5	4.14 to 8.75	2.77 to 7.39	3.89 to 8.51	4.84 to 9.46	3.88 to 8.49	3.24, 7.86
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Hedge's g	1.08	0.93	0.89	0.95	0.88	0.72	0.90	1.13	0.93	0.86

CI: Confidence interval, SD: Standard deviation, MD: Mean difference, MP: Medical Professionals

Figure 4: Peak Inspiratory Pressure (PIP) during 30-min bag-valve-mask ventilation simulation. Data are shown as mean \pm standard deviation (SD). Tables present minute-by-minute values for mean, SD, mean difference (MD), 95% confidence interval, P value, and Hedges' g. The box above each graph summarizes the overall MD, P value, and Hedges' g. (a) PIP trends over 30 min



	1	2	3	4	5	6	7	8	9	10
CV Airgency	6.30	3.30	3.10	1.80	7.30	1.00	2.20	6.10	1.30	3.00
CV MP	28.30	32.91	35.80	34.11	37.58	36.66	36.32	30.30	39.04	41.09
Difference	-22.00	-29.61	-32.70	-32.31	-30.28	-35.66	-34.12	-24.20	-37.74	-38.09
	11	12	13	14	15	16	17	18	19	20
CV Airgency	1.80	6.30	6.60	1.40	3.70	1.10	2.70	0.90	1.20	1.00
CV MP	39.45	36.26	33.18	33.49	33.51	33.71	31.80	30.79	38.61	37.06
Difference	-37.65	-29.96	-26.58	-32.09	-29.81	-32.61	-29.10	-29.89	-37.41	-36.06
	21	22	23	24	25	26	27	28	29	30
CV Airgency	6.20	3.50	2.10	1.10	1.00	1.10	1.00	1.10	1.50	3.80
CV MP	32.63	35.53	33.38	35.07	39.72	36.06	36.86	35.14	35.50	33.53
Difference	-26.43	-32.03	-31.28	-33.97	-38.72	-34.96	-35.86	-34.04	-34.00	-29.73

CV: Coefficient of variation, MD: Mean difference, MP: Medical Professionals

Figure 4: Peak Inspiratory Pressure (PIP) during 30-min bag-valve-mask ventilation simulation. Data are shown as mean ± standard deviation (SD). Tables present minute-by-minute values for mean, SD, mean difference (MD), 95% confidence interval, P value, and Hedges' g. The box above each graph summarizes the overall MD, P value, and Hedges' g. (b) Coefficient of variation of delivered PIP

cmH₂O (95% CI 5.90–6.74; *P* < 0.00001; *g* = 5.26). Effect sizes per time point ranged from -0.77 to 1.29, indicating a large difference favoring Airgency™ [Figure 4a]. No significant time (*P* = 0.9975) or interaction effects (*P* > 0.9999) were found. Airgency™ also showed a substantially lower CV (2.5% ± 1.3%) than manual ventilation (28.3%–41.1%; *P* < 0.00001; *g* = -7.61) [Figure 4b].

Fatigue level

Operator fatigue increased progressively during 30 min of manual BVM ventilation [Figure 5a] from 1.83 ± 1.11 to 5.09 ± 2.09, with a significant temporal effect (*P* < 0.0001) and between-participant variability (*P* < 0.0001). Fatigue became significant after the 5th min (*P* = 0.0046) and continued to rise throughout the session, with effect sizes (Hedges' *g*) from -0.06 to -1.93. The CV decreased from 60.35% to 40.98% [Figure 5b], indicating convergence toward uniform fatigue across participants.

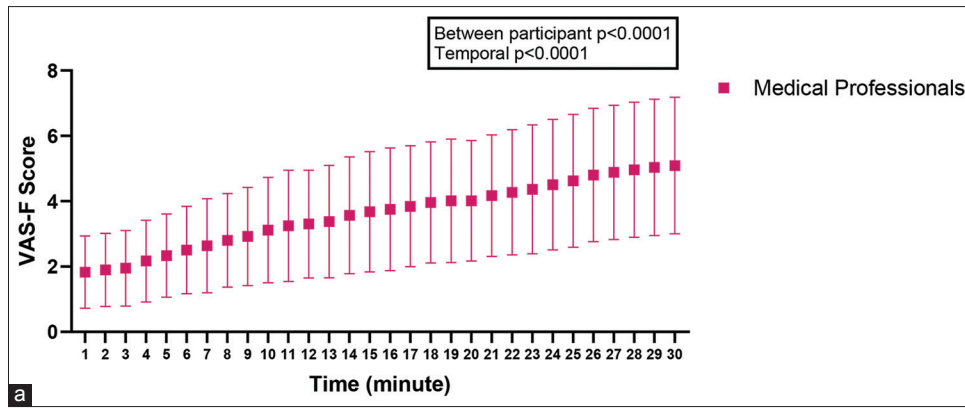
Discussion

To the best of our knowledge, this is the first simulation-based study evaluating Airgency™'s performance. The device demonstrated more consistent and stable ventilation than manual

BVM use by medical professionals. Across all parameters – BR, VT, and PIP – Airgency™ showed lower variability and tighter CIs, indicating superior control and reproducibility. While both methods achieved target ventilation, Airgency™ reduced operator-dependent inconsistencies, supporting its potential as a reliable alternative for emergency respiratory support.

Respiratory rate is crucial for effective ventilation, as excessively high rates can cause hyperventilation and alkalosis, while low rates risk hypoventilation and acidosis.^[9] Both Airgency™ and manual BVM ventilation targeted 15 breaths/min. This rate represents the upper threshold of effective ventilation, aligning with previous findings that define adequate ventilation as ≤ 15 breaths/min with a VT of 300–600 mL, corresponding to optimal ventilation cycles.^[10,11] However, manual ventilation showed extreme deviations, with rates as low as 2 bpm and as high as 60 bpm – well beyond the recommended 12–20 bpm range – highlighting the variability and potential risks associated with prolonged manual operation.

VT is critical for adequate alveolar ventilation while avoiding lung injury. Airgency™ maintained a stable VT of 397.8 ± 3.1 mL – close to the 400 mL target (≈ 6 mL/



	1	2	3	4	5	6	7	8	9	10
Mean MP	1.83	1.90	1.95	2.17	2.34	2.51	2.64	2.81	2.92	3.12
SD MP	1.11	1.12	1.16	1.25	1.27	1.33	1.44	1.43	1.50	1.61
Mean difference	Reference	6.46	6.48	7.230	6.56	6.75	5.43	6	6.69	6.01
95% CI		-0.5 to 0.37	-0.55 to 0.32	-0.77 to 0.1	-0.94 to -0.07	-1.11 to -0.24	-1.24 to -0.37	-1.41 to -0.54	-1.53 to -0.66	-1.72 to -0.85
P		>0.9999	>0.9999	0.4505	0.0046	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Hedge's g		-0.06	-0.10	-0.29	-0.42	-0.56	-0.65	-0.75	-0.84	-0.96
	11	12	13	14	15	16	17	18	19	20
Mean MP	3.25	3.30	3.38	3.57	3.68	3.75	3.84	3.96	4.01	4.01
SD MP	1.70	1.65	1.72	1.79	1.84	1.88	1.85	1.85	1.89	1.84
Mean difference	7.09	7.15	7.23	6.08	5.62	6.01	4.93	6.32	6.92	6.76
95% CI	-1.85 to -0.98	-1.95 to -1.07	-1.98 to -1.11	-2.18 to -1.31	-2.28 to -1.41	-2.36 to -1.49	-2.45 to -1.58	-2.56 to -1.7	-2.62 to -1.75	-2.66 to -1.78
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Hedge's g	-1.01	-1.01	-1.08	-1.19	-1.22	-1.25	-1.29	-1.38	-1.41	-1.39
	21	22	23	24	25	26	27	28	29	30
Mean MP	4.17	4.27	4.36	4.51	4.62	4.81	4.88	4.96	5.04	5.09
SD MP	1.86	1.92	1.97	2.00	2.03	2.04	2.05	2.07	2.09	2.09
Mean difference	6.54	6.19	5.67	6.2	6.44	5.08	6.2	7.15	6.18	5.55
95% CI	-2.77 to -1.9	-2.88 to -2.01	-2.97 to -2.1	-3.11 to -2.24	-3.23 to -2.36	-3.41 to -2.54	-3.49 to -2.62	-3.56 to -2.7	-3.64 to -2.77	-3.65 to -2.77
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Hedge's g	-1.52	-1.57	-1.60	-1.65	-1.70	-1.79	-1.83	-1.87	-1.91	-1.93

CI: Confidence interval, SD: Standard deviation

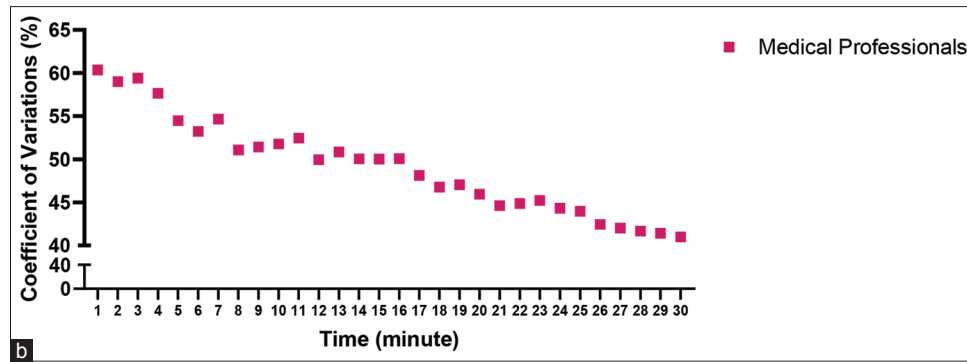
Figure 5: Medical professionals' Visual Analog Scale for Fatigue (VAS-F) score during 30-min bag-valve-mask ventilation simulation. Data are presented as mean ± standard deviation (SD). Tables show minute-by-minute values for mean, SD, mean difference from baseline, 95% confidence interval, P value, and Hedges' g. The box above the graph summarizes P values for between-participant and temporal variations. (a) VAS-F trends over 30-min

kg for a 60–70 kg adult) – with minimal variability. Manual ventilation achieved a similar mean VT (406.9 ± 85.4 mL) but showed wide fluctuations, from 10 mL (hypoventilation) to 762 mL (hyperventilation). Such extremes risk atelectasis, barotrauma, and volutrauma.^[12-14]

PIP remained below 30 cmH₂O for both groups, within safe limits.^[14] However, manual ventilation showed marked variability, with some PIP values below the optimal 20–30 cmH₂O range and occasional peaks above 40 cmH₂O, which may impair venous return and increase the risk of barotrauma or aspiration.^[15] The slightly higher PIP from Airgency™ likely results from faster inspiratory flow, shorter rise time, and reduced leakage,

yielding stable, safe pressures with minor deviations from minimal control delays.^[16]

The variability in manual BVM performance reflects its operator dependence, where technique, hand strength, and fatigue affect ventilation consistency and safety. Studies showed that male operators deliver higher VTs, glove size influences control,^[17] and experienced clinicians tend to use smaller VT and higher BR.^[18] VT and peak pressure also correlate with experience and confidence.^[19] Hyperventilation has been associated with rapid bag refilling and excessive grip force, though air leaks may help mitigate overinflation,^[20] while one-hand versus two-hand techniques significantly affect VT delivery.^[21] Feedback systems can improve



	1	2	3	4	5	6	7	8	9	10
CV MP	60.35	59.02	59.41	57.65	54.47	53.22	54.66	51.09	51.41	51.78
Difference	Reference	-1.33	-0.94	-2.70	-5.88	-7.12	-5.69	-9.26	-8.93	-8.57
	11	12	13	14	15	16	17	18	19	20
CV MP	52.44	49.94	50.85	50.05	50.02	50.06	48.13	46.77	47.05	45.95
Difference	-7.91	-10.40	-9.49	-10.29	-10.32	-10.28	-12.22	-13.57	-13.29	-14.40
	21	22	23	24	25	26	27	28	29	30
CV MP	44.61	44.86	45.21	44.33	43.97	42.44	42.02	41.68	41.41	40.98
Difference	-15.74	-15.48	-15.13	-16.02	-16.38	-17.91	-18.33	-18.67	-18.94	-19.37

CV: Coefficient of variation

Figure 5: Medical professionals' Visual Analog Scale for Fatigue (VAS-F) score during 30-min bag-valve-mask ventilation simulation. Data are presented as mean \pm standard deviation (SD). Tables show minute-by-minute values for mean, SD, mean difference from baseline, 95% confidence interval, *P* value, and Hedges' *g*. The box above the graph summarizes *P* values for between-participant and temporal variations. (b) Coefficient of variation of VAS-F

control of VT, BR, and PIP, enhancing manual ventilation accuracy.^[22]

Muscle fatigue contributed to declining performance during manual ventilation, increasing from very mild (VAS-F \approx 2) to moderate-high levels (VAS-F \approx 5). Similarly, Riggle *et al.* reported a fatigue score of 6/10 after 3 h of BVM use,^[23] and Halpern *et al.* noted exertion rising from 6.4 to 10.2 over 6 h.^[24] This progressive fatigue likely explains the greater variability observed during prolonged manual ventilation.

Limitations

This study has several limitations. First, variability in manual resuscitation may have been influenced by operator factors such as experience, physical condition, and training, which were not analyzed. Second, Airgency™ was tested in a controlled simulation that does not fully reflect real-world conditions, such as patient movement or equipment failure. Third, fatigue assessment relied on a subjective VAS-F scale, potentially introducing reporting bias.

Fourth, the 30-min observation period reflects acute rather than long-term performance. This duration simulated emergency conditions where patients with respiratory failure often require temporary manual ventilation or support during transport before a ventilator becomes available. Evidence shows noninvasive ventilation (NIV) can be effective in selected patients with mild ARDS, SARS, or H1N1, with success rates up to 48%. The Indian

Society of Critical Care Medicine recommends NIV only for hemodynamically stable patients in controlled intensive care unit settings (Level III).^[25] In low-resource environments with limited hospital access, prolonged manual hand-bag ventilation may remain the only life-saving option. Such interventions, though ethically complex, are justified under the principles of beneficence and patient welfare when no alternatives exist.^[26] In this context, Airgency™ offers a practical solution to reduce operator fatigue and variability in resource-limited conditions.

Finally, only three ventilation parameters were assessed, which may not fully capture the physiological impact of ventilation quality. Future studies should include end-tidal CO₂ and lung compliance using advanced simulators, whereas oxygenation assessment requires clinical trials. Further clinical and endurance testing is needed to validate Airgency™'s long-term safety and reliability.

Conclusion

Airgency™ demonstrated superior consistency and precision in delivering ventilation parameters – BR, VT, and PIP – compared to manual BVM ventilation by medical professionals, whose performance showed greater variability and fatigue-related decline. These findings suggest that automated systems like Airgency™ may improve the reliability of manual resuscitation by reducing operator-dependent variability and fatigue. Further studies in clinical and prolonged-use settings are needed to confirm its real-world performance and safety.

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Author contributions statement

Reza Widiyanto Sudjud: Conceptualization, Resources, Methodology, Data Curation, Writing – Review and Editing; Jenifer Kiem Aviani: Writing – original draft, Writing – Review and Editing, Visualization, Formal Analysis.

Conflicts of interest

The authors declare that Airgency™ was developed by research teams at Institut Teknologi Bandung and Padjadjaran University. Although the authors are affiliated with these institutions, they have no personal financial interests, ownership, or commercial affiliations related to the device. The study was conducted solely for academic and scientific evaluation purposes.

Ethical approval

This study was approved by the Research Ethics Committee of Padjadjaran University [Amendment No. 557/UN6. KEP/EC/2020. Clinical trial registration was not required, as the study used a manikin-based simulation with medical professionals serving only as operators, and outcomes focused solely on device performance, not human health.

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