ORIGINAL RESEARCH

Comparing positive pressure ventilation efficacy of a novel foot operated resuscitator with self-inflating bag and mask in a manikin model

Somashekhar Marutirao Nimbalkar ,[1,2] Binoy Viresh Shah,[1] Amee Atulkumar Amin,[1] Vishwa Tushar Patel,[1] Ajay Gajanan Phatak[2]

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[1]Department of Pediatrics, Pramukhswami Medical College, Karamsad, Gujarat, India
[2]Central Research Services, Charutar Arogya Mandal, Karamsad, Gujarat, India

Correspondence to
Professor Somashekhar Marutirao Nimbalkar, Department of Pediatrics, Pramukhswami Medical College, Karamsad, Gujarat, India, Pramukhswami Medical College, Gujarat 388325, India; somu_somu@yahoo.com

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ABSTRACT

Aim To compare positive pressure ventilation efficacy of a novel foot operated resuscitator (FOR) during positive pressure ventilation with that of self-inflating bag and mask (SIBM) using a manikin model.

Method A comparative trial was conducted with 117 participants at a level III neonatal intensive care unit using Baby Anne (Laerdal Medical, Norway). Flow and pressure sensors were used to measure tidal volume propelled (Vp) and delivered (Vt). Each participant delivered 60 breaths, using each device targeting adequate chest-rise defined as that corresponding to a Vt of 15–21 mL. Vt, Peak Inspiratory Pressure (PIP), Leak Percentage (%), Inspiratory Time (Ti, millisecond) and other parameters were recorded using a PC (Dell, Windows V.10) on a custom application (LabView 2014 platform NI, USA). The proportion of breaths achieving target range Vt, other key ventilation parameters and their variability were compared between a generic CE approved bag and mask and a novel FOR (*NeoBreathe*, Phoenix Medical Systems, India).

Result Using an SIBM, participants delivered a mean (SD) Vt of 17.52 (5.22) mL, achieving target range Vt in 46.99% of all breaths, with a mean (SD) face-mask leak per cent of 32.51% (22.25). Using the FOR, participants delivered a mean (SD) Vt of 18.31 (3.90), achieving target range Vt in 54.37% of all breaths and a mean (SD) face-mask leak per cent of 18.89% (14.45). Variability of Vt, PIP and leak per cent was significantly reduced with FOR.

Conclusion FOR significantly reduced face-mask leak, significantly increased the proportion of breaths achieving Vt within optimal range and could offer a novel alternative to a SIBM.

INTRODUCTION

Birth asphyxia, defined as the failure to establish breathing at birth, accounts for an estimated 813 000 deaths each year and is the third-largest cause of neonatal mortality.[1] Newborn resuscitation is known as one of the most effective life-saving public health interventions for newborns.[2] However, effective newborn resuscitation requires skill that is unavailable at most birthing facilities in low-resource countries. This barrier needs to be overcome to reduce neonatal mortality.[1 3] One of the key challenges faced by care providers in effective resuscitation is the formation of an effective face-mask seal, the lack of which leads to high and variable leakage, causing wide variability of tidal volumes (Vt) even in the hands of experts.[4] This points towards the need for an easy-to-use resuscitation device, especially in low-resource settings, where access to postpartum neonatal care is poor and the incidence, mortality and burden of long-term impairment from intrapartum-related events is the highest.[5]

Methods to reduce face-mask leakage have received considerable attention from investigators. Tracy *et al* found that applying a face-mask with two hands (made possible when an assistant compresses the bag) reduces face-mask leak by up to 50%.[6] Unfortunately, resource-constrained facilities often lack even a single skilled birth attendant, expecting two is a luxury.

NeoBreathe, a novel foot operated resuscitator (FOR) (figure 1) aims to

Figure 1 *NeoBreathe* novel foot operated resuscitator.

address this issue by freeing one hand of the operator from the task of bag compression as described below:

The key component of *NeoBreathe* is a pair of bellows enclosed in a foot pedal. Breaths are delivered to the patient when the operator presses the pedal with their foot, compressing the enclosed bellows and propelling air through a breathing circuit and a non-rebreathing valve into a connected patient-airway interface, such as a face mask or an endotracheal tube.

Such a design eliminates the compulsory dependence on a compressed gas source as in case of T-piece resuscitators (TPRs). Thus, for the first time, a two-handed mask seal is made possible in single-person resuscitation with a manually powered device. This is done to reduce face-mask leakage and to allow more consistent appropriate Vt delivery and our study seeks to find out whether this hypothesis is borne out in practice on a manikin model. Also, since movements caused by pump compression are conducted at a distance from the face-mask interface, a more stable face-mask grip can be expected. A reusable manometer and a positive end-expiratory pressure (PEEP) valve are included as standard accessories. Unlike TPR, the device does not allow delivery of continuous positive airway pressure.

Additional features claimed by the manufacturer, not investigated in the current study include: suction and broad fractional inspired oxygen regulation.

Our study seeks to answer the following questions: first, since lower limb muscles are adapted for coarse movements more than fine motor functions, can the FOR allow optimal Vt and Peak Inspiratory Pressure (PIP) delivery with adequate precision?; second, when compared with self-inflating bag mask (SIBM), how precisely can first-time users deliver positive pressure ventilation (PPV) using the FOR.

METHODS

A comparative study was conducted at a level III Neonatal Intensive Care Unit (NICU) of a tertiary care hospital, with 117 participants. The participants consisted of Interns, Residents, NICU nurses and Consultants from the Departments of Paediatrics, Anaesthesia and Obstetrics and Gynaecology. All interns and members of concerned departments were invited to participate through a public notice. Those volunteering were recruited after informed consent. No special insistence was made to participate, nor was anyone denied participation. Thus, sample size in each group was determined by the availability of participants during the study period (7 days).

An infant manikin (Baby Anne, Laerdal Medical Stavanger, Norway) was used for the study. A generic, CE-approved SIBM resuscitator was used, with pressure release at 35 cm H_2O, maximum stroke volume of 180 mL, and total bag-volume 230 mL. Performance of the pressure release in the SIBM was verified before the study. The test-lung used for the study had a static compliance of 1.6 mL/cm H_2O measured in 20 to 50 mL range. The 'upper airway' of the manikin (conduit from 'mouth' to test-lung inlet) had a resistance of 40 cm H_2O per LPM measured at 10 LPM.

One mass flow sensor, S1 (Mass Flow sensor, TSI 4143, TSI, USA) was connected at the patient port, to measure the volume of air being propelled (Vp), and another one, S2, was connected at the test lung inlet, to measure actual Vt delivered to the test lung.

Leak and leak percentage were calculated by subtracting the Vt delivered from the propelled volume yielding the leak volume. Pressure and volume data from these sensors were logged and displayed graphically and numerically on a screen to the participants in real-time during the practice and training sessions.

A Neonatal Resuscitation Programme (NRP) certified faculty determined the optimal chest rise for the study setup. This chest rise corresponded with a Vt of 15–21 mL which was defined as the optimal Vt or target range Vt. At the rate of 5–7 mL per kg, this corresponded to a 3 kg term newborn. Participants were instructed to carry out PPV on the manikin, targeting such optimal chest rise and corresponding target range Vt. Study setup is shown in figure 2. More details are given in online supplementary file 1.

Participants were oriented to the setup, followed by some practice time. Audio alerts (in the forms of low, medium and shrill beeps) were delivered during practice time to accelerate learning. During the training and orientation, participants were allowed to develop an understanding of the optimal chest-rise associated with target range Vt as seen on the screen. All participants, including interns with no prior training, were thus trained (or retrained as needed) in the use of both

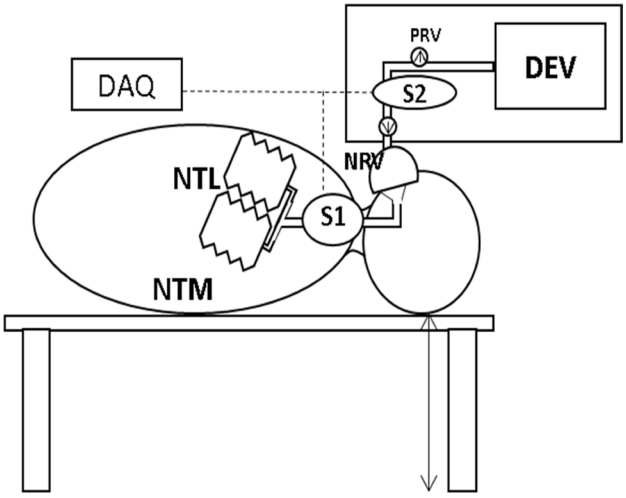

Figure 2 Study setup. DAQ, data acquisition system; DEV, resuscitation device; NRV, non return valve; NTL, neonatal test lung; NTM, neonatal test manikin; PRV, pressure release valve; S1 and S2, first and second flow and pressure sensors.

devices. Training time was strictly limited to 2–5 min for both devices to maintain uniformity. On completion of practice and training time, a mock recording of 60 breaths was done. For both devices, one additional mock recording of 60 breaths was provided for participants achieving target range Vt with less than 20% breaths. After this, the participants commenced the prefinal pair of sessions—irrespective of performance. During the prefinal pair of recordings with SIBM and FOR, participants were allowed to observe delivered pressure and Vt data in real-time on a computer screen (without audio alerts). After this period of orientation and training—actual data recording was commenced—for 60 breaths with each device, with participants targeting optimal Vt delivery by looking at chest rise alone—with no access to real-time data display.

Experienced participants had significant experience in using SIBM—whereas this was their first exposure to FOR. To partially offset this asymmetry, data were recorded first with bag mask and subsequently with FOR, for all participants.

For study-data recording, all participants were instructed to use the single-handed EC clamp mask holding technique while using SIBM and two-handed mask grip while using FOR.[6]

PIP, Leak Percentage and Vt were recorded using a specially developed application (LabView 2014 platform National Instruments, USA). Accuracy of the recording systems was as follows: Flow (sensor accuracy): ±2% of reading or 0.005 LPM whichever is greater and a response time of 4 mS (since flow rarely exceeds 10 LPM during newborn resuscitation, the accuracy would be ±0.2 LPM), Pressure (sensor accuracy): ±1 Kpa absolute mode accuracy (used in differential mode for at least 1000x accuracy), Volume: accuracy of software that integrated flow data from the sensor to calculate volume was determined to be +/- 1 ml by measuring the volume of a 20 mL syringe.

Screenshots of the data recording interface provided in figure 3. Recorded data were analysed using SPSS version 14 software (IBM) including descriptive statistics for the study population and group statistics for various parameters of interest. Factorial analysis of variance was used to determine the main effects of the device and specialty of users. Initial training and observational assessment were carried out by a neonatal fellow from the NICU—with NRP-certified training.

RESULTS

Of the 117 healthcare providers assessed for PPV skills using SIBM and FOR, 43 were interns, 25 were nurses, 26 were residents/fellows and 23 were consultants (figure 2). Interns were categorised as the 'no experience' group due to lack of resuscitation training and experience prior to the study. All the remaining

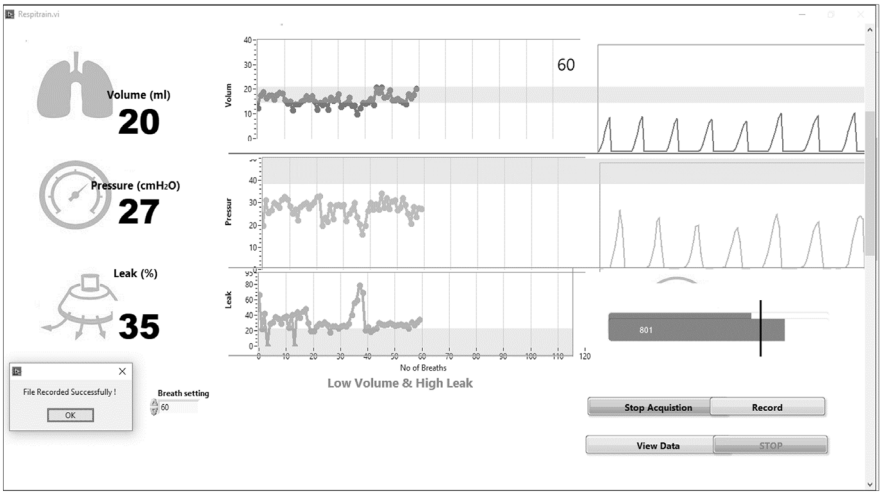

Figure 3 Data capture screenshot.

Table 1 Primary performance parameters of SIBM and FOR

	No experience		Some experience		Overall	
	SIBM n=2453	FOR n=2361	SIBM n=4261	FOR n=4167	SIBM n=6714	FOR n=6528
Tidal volume (mL)	16.82 (5.23)	18.04 (3.78)	17.92 (5.18)	18.46 (3.96)	**17.52** (5.22)	**18.31** (3.90)
P value, mean diff. (95% CI of difference)	<0.001, –1.22 (–1.48 to –0.96)		<0.001, –0.53 (–0.73 to –0.33)		<0.001, **–0.78 (–0.94 to –0.63)**	
PIP (cmH_2O)	19.86 (5.98)	19.99 (4.24)	22.05 (6.38)	20.16 (3.93)	**21.25** (6.33)	**20.10** (4.04)
P value, mean diff. (95% CI of difference)	0.38, –0.13 (–0.43 to –0.16)		<0.001, 1.90 (1.67 to 2.12)		<0.001, **–0.92 (–0.97 to –1.33)**	
Leak%	31.82 (23.19)	16.76 (14.83)	32.91 (21.69)	20.09 (14.09)	**32.51** (22.25)	**18.89** (14.45)
P value, mean diff. (95% CI of difference)	<0.001, 15.06 (13.96 to 16.16)		<0.001, 12.82 (12.04 to 13.60)		<0.001, **13.63 (12.99 to 14.26)**	
Leak (mL)	10.25 (10.58)	4.18 (5.51)	11.66 (11.61)	5.28 (4.69)	**11.14** (11.26)	**4.88** (4.66)
P value, mean diff. (95% CI of difference)	<0.001, 6.07 (5.62 to 6.53)		<0.001, 6.38 (6.00 to 6.75)		<0.001, **6.26 (5.97 to 6.55)**	
Inspiratory time (milliseconds)	346.04 (142.72)	378.11 (144.20)	357.37 (134.94)	386.42 (141.14)	**353.23** (137.93)	**383.42** (142.30)
P value, mean diff. (95% CI of difference)	<0.001, –32.07 (–40.18 to –23.96)		<0.001, –29.05 (–34.95 to –23.16)		<0.001, **–30.19 (–34.96 to –25.41)**	
Pressure drop through 'upper airway' (cmH_2O)	4.28 (2.69)	2.80 (1.49)	5.56 (4.64)	3.22 (1.97)	**5.09** (4.09)	**3.07** (1.82)
P value, mean diff. (95% CI of difference)	<0.001, 1.47 (1.35 to 1.60)		<0.001, 2.34 (2.19 to 2.49)		<0.001, **2.02 (1.92 to 2.13)**	
Propelled volume (mL)	27.02 (10.49)	22.11 (5.38)	29.55 (11.85)	23.67 (6.12)	**28.63** (11.44)	**23.11** (5.91)
P value, mean diff. (95% CI of difference)	<0.001, 4.90 (4.43 to 5.37)		<0.001, 5.88 (5.48 to 6.28)		<0.001, **5.52 (5.21 to 5.83)**	

Bold values signify significant statistical differences.
FOR, foot operated resuscitator; PIP, peak inspiratory pressure; SIBM, self-inflating bag and mask.

participants were categorised into the 'some experience' group.

At 60 breaths per participant per device, a total of 14 040 breaths were delivered—2580 per device in the 'no-experience' group (n=43) and 4440 per device in the 'some-experience' group (n=74). Of these, the system failed to capture 150 breaths (1.07% data loss) and 5.68% of the recorded breaths were expunged due to invalidity—giving a cleaned data set as follows:

In the 'no-experience' group, 2453 breaths with SIBM and 2361 with FOR (total 4814).

In the 'some-experience' group, 4261 breaths with SIBM and 4167 with FOR (total 8428). A total 6714 breaths with SIBM and 6528 with FOR were recorded across all groups, totalling up to 13 242 breaths.

A few participants who required and obtained one additional session each because of failure to achieve 20% target Vt delivery in the first attempt were: seven interns (four for FOR, three for SIBM), five nurses (four for FOR, one for SIBM), two residents (both for FOR) and three consultants (two for FOR and one for SIBM).

A comparison of the primary performance parameters between SIBM and FOR devices is presented in table 1. The findings are divided into 'no-experience' and 'some-experience' groups.

As described previously, the following target ranges were set: Vt: 15–21 mL, PIP: 15–40 cmH_2O and face-mask leak of <30%. A comparison between the two devices in achieving these secondary parameters is presented in table 2.

The Vt is delivered more often in the ideal range with the FOR as compared with SIBM, especially with bag and mask delivering Vt below target range more often. These details can be seen in table 3. The maximum Vt is higher in the bag and mask and can cause volutrauma to the newborn lung while it is reasonably high at 31.12 mL with FOR. The SD and CV for Vt are much higher with SIBM, indicating higher variability of delivered tidal volume (table 4).

Figures 4–7 provide a visual representation of some of the results.

DISCUSSION

SIBM is in use across the world for over five decades due to its compactness, affordability, simple construction, universal availability, global familiarity and independence from elaborate expensive equipment. Several studies have emphasised the variability of Vt delivered by bag mask, due to high and variable face-mask leakage.[7] It does not allow setting of PIP to a fixed value, though PIP may be regulated by how the bag is pressed.

In contrast, the TPR frees one hand of the operator from bag compression, by employing compressed gases to power PPV. It also allows operators to deliver preset

Table 2 Secondary performance parameters of SIBM and FOR (all figures are in %)—95% CIs based on X^2 test

	No experience		Some experience		Overall	
Percentage of breaths with:	SIBM n=2453	FOR n=2361	SIBM n=4261	FOR n=4167	**SIBM n=6714**	**FOR n=6528**
Tidal volume (mL) in target range (15—21 mL)	46.60	57.09	47.22	52.82	**46.99**	**54.37**
P value, difference in % (95% CI)	<0.001, –10.50 (–13.31 to –7.69)		<0.001, –5.60 (–7.73 to –3.47)		<0.001, **–7.37 (–9.07 to –5.68)**	
PIP in target range (15–40 cmH_2O)	78.76	86.66	87.73	89.46	**84.45**	**88.45**
P value, difference in % (95% CI)	<0.001, –7.90 (–10.02 to –5.78)		<0.001, –1.74 (–3.00 to –0.38)		<0.001, **4.00** (–5.16 **to –2.84**)	
Face-mask leak % <30%	56.34	84.96	54.99	79.24	**55.48**	**81.31**
P value, difference in % (95% CI)	<0.001, –28.62 (–31.06 to –26.19)		<0.001, –24.25 (–26.19 to –22.32)		<0.001, **–25.83 (–27.35 to –24.31)**	

Bold values signify significant statistical differences.
FOR, foot operated resuscitator; PIP, peak inspiratory pressure; SIBM, self-inflating bag and mask.

inflation pressures and is superior to bag mask in the consistent delivery of PIP and PEEP.[8] However, the poor availability of compressed medical air, required expertise, and the high cost of air-O_2 blender make TPR unsuitable for resource-constrained settings.

From manikin studies, advantages of the TPR include the delivery of inflating pressures closer to predetermined target pressures with least variation, the ability to provide prolonged inflation breaths and more consistent Vt. Disadvantages include a technically more difficult setup, more time required to adjust pressures during resuscitation, a larger mask leak and less ability to detect changes in compliance. A study done in 11 centres from 5 countries (Argentina, Chile, Peru, Italy and the USA), compared the effectiveness of the TPR and the SIBM in providing ventilation to newborns at birth. Their study showed that the use of the TPR decreased intubation rate and the maximum pressure applied.[9]

The manufacturer of FOR used in the study discloses a maximum retail price of US$400–700 for various versions (approx. US$1=Rs71). The average price rests between SIBM and TPR and cannot be directly compared with either, given multiple functions other than PPV. FOR is a purely mechanical device and works without a power source. According to product literature, the device is reusable, user-serviceable and can be disinfected through autoclaving, and chemical means—the cheapest of which is the use of quaternary ammonium compounds, with an estimated cost of US$0.10 for each instance.

On analysis of the results of our study, we find that mean Vt delivered using FOR was higher than that delivered by SIB, while the mean PIP generated using FOR was lower than that with SIBM. PPV with FOR demonstrated a significantly reduced variability compared with SIBM (figure 3) in both parameters signifying increased consistency in the delivery of Vt and PIP. A higher mean Vt with a lower mean PIP achieved with FOR could potentially be attributed to the increased Ti associated with this device. As airway resistance is directly proportional to flow rate, a longer Ti could be associated with more effective ventilation.

A high and variable face-mask leakage has been identified as the single most important factor in reducing the effectiveness of PPV with SIBM. In our study, the mean (SD) face-mask leakage when using SIBM was 10.25 (10.58) mL or 31.82 (23.19)% in the 'no-experience' group while it was reduced to 4.18 (5.51) mL or 16.76 (14.83%) when using FOR. Breaths with a face-mask leak percentage <33.33% were defined as low leak breaths. While using FOR, participants could achieve low leak in 81.31% of breaths compared with 55.48% with SIBM (table 2) indicating significantly reduced face-mask leakage.

These results are supported by Tracy *et al*, who used SIBM for their study and employed two persons to achieve a two-handed face-mask seal.[6] Using FOR, a single person can achieve a two-handed face-mask seal and thus achieve a similar, 42% reduction in leakage.

A mere reduction in leakage means little unless it translates to more effective PPV.

Table 3 Frequency distribution of breaths below, within and above target range Vt

Percentage of breaths in respective tidal volume ranges		SIBM		FOR		P value
		No.	Percentage	No.	Percentage	
Vt <15 mL	Inadequate Vt	2073	30.88	1287	19.71	<0.001
Vt 15–21 mL	Optimal Vt	3152	46.95	3549	54.36	<0.001
Vt >21 mL	Excessive Vt	1489	22.18	1693	25.93	<0.001
	Total	6714		6529		<0.001

FOR, foot operated resuscitator; SIBM, self-inflating bag and mask; Vt, tidal volume.

Table 4 Descriptive statistics of tidal volume

	SIBM	FOR	P value
Minimum	5.06	0.50	<0.001
Maximum	43.56	31.12	<0.001
Mean	17.52	18.31	<0.001
Median	17.49	18.43	<0.001
Mode (rounded)	18	18	
SD	5.22	3.90	<0.001
CV	27.29	15.22	

CV, coefficient of variation; FOR, foot operated resuscitator; SD, standard deviation; SIBM, self-inflating bag and mask.

In order to assess this, we defined a target range of 15–21 mL as optimal Vt, corresponding to the level of optimal chest rise in the study manikin, and participants were instructed to try and achieve this target range by looking at chest rise. While using FOR, 'no-experience' and 'some-experience' participants achieved target range Vt in 57.09% and 52.82% of delivered breaths, respectively. While using SIBM, participants achieved the same in 46.60% and 47.22% breaths, respectively (table 2). On combined analysis, the use of FOR was associated with an increase of 15.70% (from 46.99% to 54.37%) in the proportion of breaths delivering optimal Vt, indicating a significantly increased precision and effectiveness of PPV in this manikin model.

Improper use of any resuscitation device can lead to barotrauma and volutrauma (because of high PIP and Vt), atelectotrauma (due to improper PEEP), and super oxygenation injuries to the lung and other organs (due to excess FiO_2).[10 11] For instance, Bassani *et al* found that most professionals generated very high inspiratory pressure and Vt, especially when both hands were used to ventilate, increasing the risk of barotrauma and volutrauma, while others provided pressures and volumes so low that they would be insufficient for adequate pulmonary expansion and could lead to hypoventilation.[12] Given its critical importance, training of caregivers in newborn resuscitation has received tremendous importance and allocation of public health resources in the last decade. A resuscitation device which can be rapidly learnt and mastered would be a significant advance.

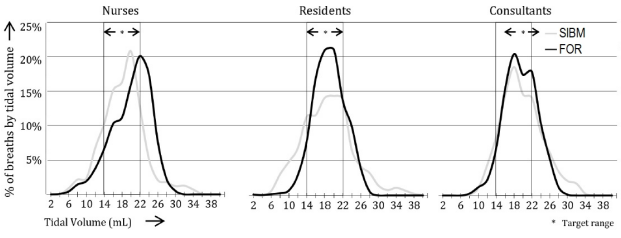

Figure 4 Frequency distribution of tidal volume for breaths delivered by SIBM and FOR across different participant groups. FOR, foot operated resuscitator; SIBM, self-inflating bag and mask.

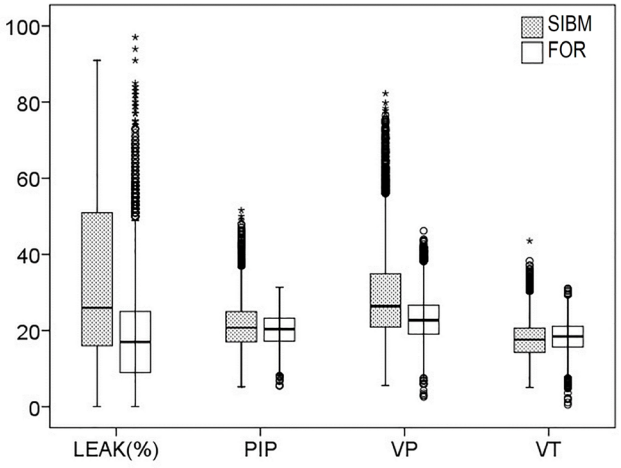

Figure 5 Box plot showing variability in primary and secondary parameters between SIBM and FOR. *, **, *** are all outliers. FOR, foot operated resuscitator; PIP, Peak Inspiratory Pressure; SIBM, self-inflating bag and mask; Vp, volume propelled; Vt, tidal volume delivered.

LIMITATIONS

Despite taking due care, there were some limitations in our current study. We would like to acknowledge these here with a hope that they may be addressed in future work. The sequence of use of test and control devices was not randomised, intending to partially offset the asymmetry between years of experience with SIBM and none with FOR. The sample size was determined through the availability of participants during the study period. FOR had an integrated manometer, while SIBM used did not have a manometer. This was done to simulate a real-world scenario in resource-constrained settings.

CONCLUSION

Currently, most of the commonly used manual resuscitation devices require two trained professionals to achieve maximal efficiency, which is a luxury in emergency care situations in low-income and middle-income

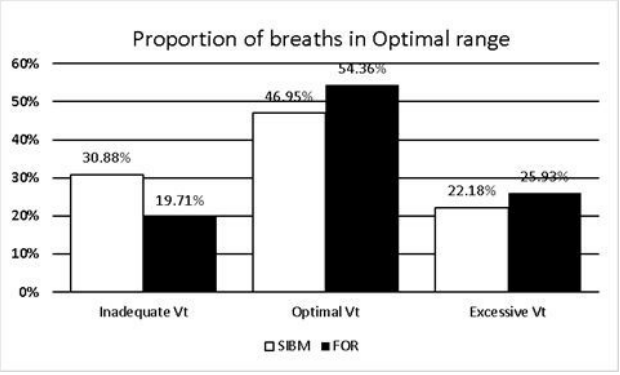

Figure 6 Bar graph showing the frequency distribution of breaths below, within and above target range Vt. FOR, foot operated resuscitator; SIBM, self-inflating bag and mask; Vt, tidal volume delivered.

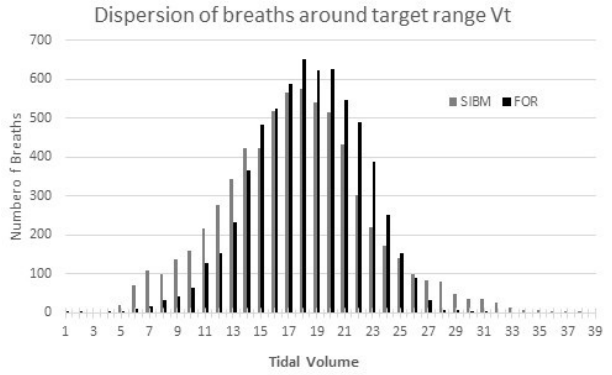

Figure 7 Histogram showing the frequency distribution of Vt. FOR, foot operated resuscitator; SIBM, self-inflating bag and mask; Vt, tidal volume delivered.

countries like India. Our results indicate that based on parameters studied, FOR was associated with a significantly improved PPV performance and significantly reduced face-mask leakage in a manikin setup, compared with SIBM. FOR could offer a novel alternative to a self-inflating bag-mask resuscitator and is worth investigating further, especially for use in resource and skill-constrained settings.

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Contributors SMN conceived, designed and conducted the study, and is the guarantor for the overall content. BVS and VTP collected the data and contributed to the final manuscript preparation. AGP conducted the statistical analysis and contributed to the final manuscript preparation. AAA assisted in statistical interpretation and manuscript writing and contributed to the final manuscript preparation and submission.

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ORCID iD
Somashekhar Marutirao Nimbalkar http://orcid.org/0000-0003-2825-2819

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