


ORIGINAL RESEARCH

Airway

Use of a novel pedal-operated compressor is non-inferior to the use of a standard hand-compressed bag-valve mask

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Abstract

Background: The standard bag-valve mask (BVM) used universally requires that a single healthcare practitioner affix the mask to the face with 1 hand while compressing a self-inflating bag with the second hand. Studies have demonstrated that creating a 2-handed seal (with 2 healthcare practitioners) is superior. Our study aims to assess the efficacy of a novel single-practitioner BVM device that uses a foot pedal as the bag compressor, allowing both hands to be available for the seal to facilitate delivery of appropriate tidal volumes during single-practitioner resuscitation.

Methods: This was a prospective, randomized, cross-over study. Participants with various BVM ventilation experience performed 2 minutes of metronome-guided BVM ventilation using a standard BVM and the pedal-operated compressor on a high-fidelity simulation mannequin. Analysis examining differences in mean tidal volume delivered was conducted using a regression model that adjusted for covariates. A secondary analysis using a series of Wilcoxon tests was conducted to compare differences in the additional out-of-range sensed breaths metrics to compare differences by prior BVM ventilation experience.

Results: A total of 58 subjects participated. The pedal-operated compressor unadjusted mean tidal volume delivered was 446.5 mL (95% confidence interval [CI], 425.9–467.1) compared with 340.6 mL (95% CI, 312.2–369.0) by standard BVM (mean change, 105.9 mL [95% CI, 71.2–140.6]; $P < .001$). When modeling a generalized estimation equation regression model, standard BVM ventilation provided a mean difference of 105.9 mL less than pedal-operated compressor ventilation after adjusting for covariates ($P = 0.01$). For the secondary outcome, the pedal-operated compressor did have a significantly lower median number of out-of-range breaths (median, 3; interquartile range [IQR], 1–11.5) compared with the standard device (median, 13.5; IQR, 6–19; $P < 0.001$).

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Conclusions: Use of a novel pedal-operated compressor may allow a single healthcare practitioner, regardless of prior experience, to deliver consistent, appropriate tidal volumes with more ease compared with the standard BVM during manual respiratory resuscitation.

KEYWORDS

critical care, emergency medicine, inventions, resuscitation, tidal volume, ventilation

1 | INTRODUCTION

1.1 | Background

Bag-valve-mask (BVM) ventilation is a critical life-saving intervention for airway management in patients whose respiratory drive is insufficient to effectively ventilate and oxygenate. This is especially important in settings where healthcare practitioners are not trained in advanced airway maneuvers such as intubation. BVM ventilation can be used indefinitely until an advanced airway is established.^{1,2} Traditionally, BVM is performed by creating a seal with a face mask over the nose and mouth with 1 hand while compressing a self-inflating bag with the other hand to provide positive pressure ventilation.³ The seal quality is critical for effective ventilation.

1.2 | Importance

The ergonomics of BVM ventilation requires pushing on the face with the index finger and thumb while lifting the jaw into the mask with the middle, ring, and pinky fingers. This operation proves difficult for many clinicians, especially those with smaller hands.⁴ This is made more challenging if the patient is obese or has a beard.⁵ Studies have shown that a large percentage of ventilation is inadequate as a result of weak grip strength and other challenges associated with operating existing BVM devices.^{6,7} Research demonstrates that creating a 2-handed seal is superior to a single-handed seal, allowing for more reliable tidal volume delivery during resuscitation with minimal fatigue.⁸⁻¹⁰ However, this technique requires 2 dedicated airway personnel, which is not always feasible or ideal in less-resourced settings. These include settings where limited staff are available for resuscitations, such as some community hospitals, and settings where space is limited at the head of the bed such that 2 healthcare practitioners cannot feasibly provide 2-person, dedicated airway management simultaneously (eg, an ambulance). Having a pedal-operated compressor, which requires minimal physical space, can be an effective means to provide a 2-handed seal with a single healthcare practitioner and thus deliver more effective ventilation in the emergency setting.

1.3 | Goals of this investigation

We aimed to compare the efficacy of a pedal-operated compressor, a novel single-practitioner BVM device that uses a foot pedal as the bag compressor, against a standard self-inflating BVM device. The

addition of a foot pedal introduces a “third limb” allowing for a single healthcare practitioner to use a 2-handed seal. We hypothesized that allowing both hands to be available to create a seal on the face would allow for efficient delivery of appropriate tidal volumes during single-practitioner respiratory resuscitation. Delivering and measuring appropriate tidal volume is the optimal metric of effective manual ventilation as established by manufacturers and prior research.¹¹⁻¹⁵

2 | METHODS

2.1 | Study design and population

We conducted a prospective, randomized, cross-over study comparing the efficiency of a prototype of a pedal-operated compressor to the standard BVM. We performed the study at Rhode Island Hospital's Lifespan Medical Simulation Center. The study population was composed of emergency medical service (EMS) practitioners, advanced practice practitioners, attending physicians, and resident physicians from emergency medicine and non-emergency medicine specialties. Participants delivered ventilations to a high-fidelity simulation mannequin with the standard BVM device and the pedal-operated compressor. The Institutional Review Board at Lifespan Corporation approved the study before its initiation.

2.2 | Selection of participants

We recruited a convenience sample of healthcare practitioners with varying levels of experience in respiratory resuscitation. Participants were recruited by email and during routine graduate medical education didactic sessions. Inclusion criteria included healthcare practitioners such as EMS practitioners, residents, advanced practice practitioners, fellows, and attending physicians who were board certified or board eligible in emergency medicine, pediatric emergency medicine, pediatrics, critical care, internal medicine, orthopedics, cardiology, or dentistry. Eligible participants were categorized into 1 of 3 specific population groups: (1) pediatric emergency medicine/emergency medicine practitioners, (2) EMS practitioners, and (3) non-pediatric emergency medicine/emergency medicine practitioners. Exclusion criteria included non-clinicians and those who are not EMS practitioners as well as individuals with physical impairments that hindered use of a standard BVM. Before starting the study, participants were asked to

The Bottom Line

Bag-mask ventilation with a single healthcare practitioner is challenging, and often there is significant mask leak. In a cross-over randomized trial with 58 participants performing ventilation on a mannequin, a novel pedal-operated bag compressor resulted in higher delivered tidal volumes compared with a traditional bag-mask device, and more breaths were delivered within a prespecified safe range.

complete a brief questionnaire regarding the following: sex, profession, profession specific role, years of experience in their profession, number of real-life clinical scenarios they had with prior BVM ventilation experience, hand dominance, and hand size. We obtained verbal consent from all participants.

2.3 | Novel pedal-operated compressor

The pedal is designed as an additional component for currently existing BVMs and is placed on the floor. A custom 3-dimensional-printed class 2 lever pumps the bag when applying force in the vertical direction with the user's foot. A flexible respiratory pipe indexes with the valve and mask. The respiratory pipe extends the mask from the floor to the patient's face. A tension spring attached to the lever allows the bag to inflate quickly after the bag is compressed to give a breath (Figure 1).



FIGURE 1 Participant using the novel pedal-operated device on a high-fidelity mannequin

2.4 | Intervention and comparison condition

After completing this questionnaire, participants were given an 8-minute interactive teaching session on how to appropriately use both devices. Participants were allowed to make adjustments (eg, change the height of the bed, adjust placement of the device on the floor) to optimize breath delivery with both devices.

Participants were randomly assigned by coin flip to give metronome-guided breaths to a high-fidelity, 70-kilogram mannequin (Laerdal Sim Man 3G, Stavanger, Norway) with 1 of the 2 devices. After a 2-minute rest period, they were instructed to give metronome-guided breaths with the other device. Participants were guided to give a breath every 6 seconds for 2 minutes, for a total of 20 breaths for each device. Tidal volume data were collected with simulation software through the mannequin. The mannequin display was concealed so that study participants were could not see the measured volumes.

Upon completion of breath delivery with both devices, participants were asked to fill out a concluding questionnaire about the ease of use of each device (Likert scale 1–5) as well as their preference for 1 device over the other. They were also given the opportunity to give subjective, open-ended feedback on the use of each device.

2.5 | Outcome

This study compared the absolute values of the mean tidal volumes delivered by participants using the pedal-operated compressor compared with the standard device.

2.6 | Sample size

Sample size was calculated using data from the Zobrist study, which reported a significantly mean higher tidal volume with the modified compared with standard BVM.¹⁶ Using the Zobrist data for this study, an expected mean difference of 90 mL end tidal volume between the standard BVM and the pedal-operated compressor, a sample size of between 55 and 60 participants, measured on both devices, would provide a statistical power of between 0.80 and 0.90 to detect a statistical difference, ($\alpha < 0.05$).

2.7 | Analysis

Screen recordings of the Laerdal Sim Man 3G (Stavanger) tidal volume display were exported as individual videos for each intervention performed by the participants. The WebPlotDigitizer image analysis tool (A. Rohatgi, WebPlotDigitizer, Version 4.2; <https://automeris.io/WebPlotDigitizer>) was used to extract the chronological time (x-axis) and tidal volume (y-axis) values of each detected breath recorded in bar graph format from the video recordings. Tidal volume and chronological time data were exported in .csv format for statistical analysis.

TABLE 1 Characteristics of Study Sample

Characteristic	Sample, N = 58	Standard BVM first presentation, n = 31	Pedal-operated BVM first presentation, n = 27
Female sex, n (%)	36 (62)	18 (58)	18 (67)
Profession, n (%)			
Paramedic/EMT	4 (5)	1 (3)	3 (11)
Emergency medicine/pediatric emergency medicine practitioner	28 (49)	13 (42)	13 (48)
Non-emergency medicine practitioner	26 (46)	17 (55)	11 (41)
Years in profession, median (IQR)	5 (2–14)	5 (2.8–11)	5 (1.5–17.5)
Approximate number of prior total patients BVM ventilated in the past, n (%)			
<10	20 (35)	11 (35)	9 (35)
10–19	6 (10)	3 (10)	3 (10)
20–29	4 (7)	3 (7)	1 (7)
≥30	28 (48)	14 (48)	14 (48)
Shoe size, range			
Female	6–11	6–10	6–11
Male	8.5–13	8.5–13	10.5–13
Handedness, n (%)			
Ambidextrous	3 (5)	2 (5)	1 (5)
Left dominant	7 (12)	2 (12)	5 (12)
Right dominant	48 (83)	27 (83)	21 (83)

Abbreviations: BVM, bag-valve mask; EMT, emergency medicine technician; IQR, interquartile range.

To adjust for other factors that could account for ventilation performance, we assessed and included the following in the regression model: prior experience in conducting BVM, clinical experience, hand size, and handedness.^{17,18}

The data were exported into SAS (Version 9.4; SAS Institute) for analysis. Descriptive statistics were reported as mean with 95% confidence interval (CI), median with interquartile range (IQR), or frequency (percentage). In addition to measuring tidal volume across sensed breaths, the following additional metrics were generated for out-of-range metrics: number of missed breaths, number of breaths out of range, number of breaths <400 mL, and number of breaths >700 mL. The upper and lower limits of in-range versus out-of-range breaths were based on conventional ventilation strategy goals of tidal volumes as recommended by the American Heart Association for BVM ventilation during basic life support between the range of ≈6 to 10 mL/kg.^{19–21}

To test the difference in average tidal volume between the 2 devices for sensed breaths (standard vs pedal-operated compressor) across participants, a generalized estimation equation regression model was conducted to allow for the effect of clustering in the data (each participant measured twice). Covariates in this model were professional role, patient bag mask use experience (4 categories: <10, 10–19, 20–29, ≥30), years of practice experience (3 categories: <5, 5–15, >15), healthcare practitioner role (emergency medicine vs not) handedness

(right and ambidextrous vs left), and hand size in centimeters (base of palm to tip of middle finger and across widest portion of palm). An ordering variable was added into the model to assess if the effect of the device was independent of the order in which it was presented to the participants.

A secondary analysis was conducted to compare differences in the additional out-of-range sensed breaths metrics. The difference between median numbers of these metrics was tested using a series of Wilcoxon tests. Differences in frequencies of participant's ratings of ease of use of both devices measured by Likert scale was tested using chi-square statistics.

3 | RESULTS

3.1 | Characteristics of study participants

Of 63 participants who were recruited, 58 participants participated in the study, and the characteristics of this sample are shown in Table 1. Most of the participants were women (n = 36, 62%) and were attending physicians or resident trainees (n = 54, 95%), with most of these participants working in emergency or pediatric emergency medicine. BVM experience with >30 patients was reported by 50% of the participants and was significantly more often reported by emergency

TABLE 2 Standard Versus Pedal-Operated BVM Ventilation Performance

Ventilation performance	Standard BVM	Pedal-operated BVM
Mean (95% CI) tidal volume, mL	340.6 (312.2–369.0)	446.5 (425.9–467.1)
Median (IQR) number of out-of-range breaths	13.5 (6–19)	3 (1–11.5)
Median (IQR) number of breaths <400 mL	12.5 (5–18)	3 (0–11)
Median (IQR) number of breaths >700 mL	0 (0–0)	0 (0–0)

Abbreviations: BVM, bag-valve mask; CI, confidence interval; IQR, interquartile range.

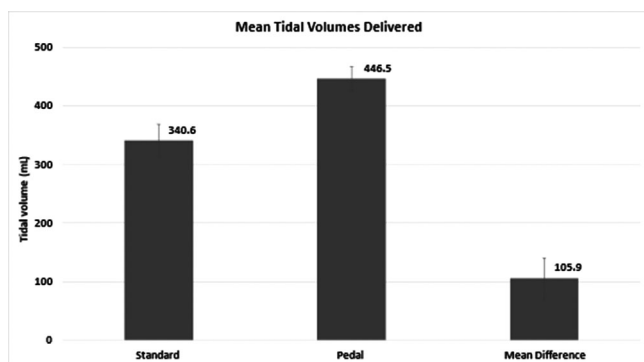


FIGURE 2 Mean tidal volumes delivered

medicine providers ($n = 19$, 70%) and paramedics ($n = 3$, 100%) than non-emergency medicine providers ($n = 5$, 19%). Most participants were right handed ($n = 48$, 83%), and 3 were ambidextrous (5%). The median number of years of experience was 5 years (IQR, 2–14). There were no significant differences between the participant characteristics in either the standard BVM group or the pedal-operated compressor (see Table 1).

3.2 | Main results

Table 2 displays the main results of the standard BVM compared with the pedal-operated compressor. The unadjusted average tidal volume of sensed breaths was significantly greater for the pedal-operated compressor (mean, 446.5 mL; 95% CI, 425.9–467.1) compared with the standard device (mean, 340.6 mL; 95% CI, 312.2–369.0; Figure 2). A regression analysis was conducted (Table SA) to assess differences in the bag device after adjusting for covariates. Standard BVM ventilation provided a mean difference of 105.9 mL less than pedal-operated compressor ventilation after adjusting for covariates ($P = 0.01$). The order in which the 2 devices were presented did not have a significant effect on tidal volume ($P = 0.48$). Years of practice, professional role, BVM ventilation experience, handedness, and hand size were also insignificant in the regression model of average tidal volume.

3.3 | Secondary analysis

For each device there was no difference in the median number of missed breaths or breaths >700 mL. As demonstrated in Table 2, the pedal-operated compressor did have a significantly lower median number of out-of-range breaths (median, 3; IQR, 1–11.5) compared with the standard device (median, 13.5; IQR, 6–19; $P < 0.001$). The pedal-operated compressor also had fewer breaths <400 mL (pedal median, 3; IQR, 1–11.5; standard median, 12.5; IQR, 5–18; $P < 0.001$).

3.4 | Qualitative data

The standard bag device was described with a Likert scale as easy or very easy to use by 41% of participants (95% CI, $\pm 13\%$) compared with 81% (95% CI, $\pm 11\%$) of participants ascribing this to the pedal-operated compressor (Figure 3). When asked about preference for device, 73% (95% CI, $\pm 12\%$) of participants favored the pedal-operated compressor.

4 | LIMITATIONS

This is an in vitro study where the participants were asked to perform BVM ventilation on a high-fidelity mannequin. We recognize that respiratory resuscitation on a mannequin may not fully translate into the experience of performing PVM ventilation on a human. If repeated, future studies should include in vivo experimental settings with animal models or humans in controlled settings such as the operating room after the induction of anesthesia. In addition, participants were aware that the device was an invention by the primary investigator and research team of the study, which could lead to biases when giving positive or constructive feedback on reactions toward using both the standard and pedal-operated compressor. We tried to mitigate these biases by using a research assistant not from the primary institution to recruit and administer the study. Another limitation is that detailed ventilatory pressures were not measured (eg, inspiratory pressures, inspiratory flow, percent leak). Lastly, the same pedal-operated compressor was used among all study participants, which led to the risk of wear and tear as the study progressed. Analysis of the data did not suggest that repeated use of the same device influenced results. If economically feasible in the future, we would have several devices available for participants to rotate through and use.

5 | DISCUSSION

Dual-practitioner BVM ventilation is consistently superior to single-practitioner BVM ventilation. This finding is attributed to the ability to more effectively create a seal and consequently deliver a reliable respiratory rate and higher tidal volumes.^{8,22} Challenges faced by clinicians providing single-practitioner ventilation include hand fatigue,

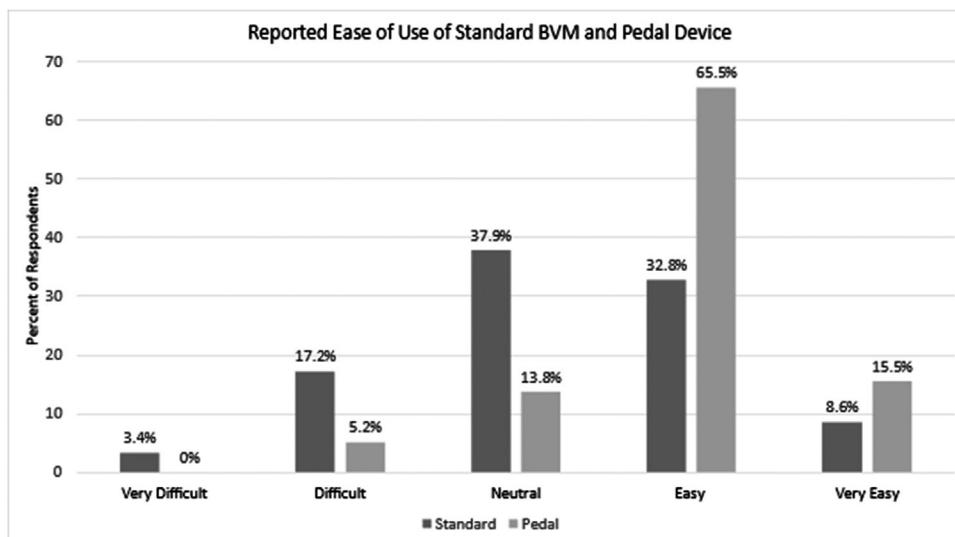


FIGURE 3 Reported ease of use of standard bag-valve mask (BVM) and pedal device

small hand sizes, and weak hand grip regardless of prior experience in BVM ventilation.²³ Unfortunately, emergent scenarios often occur where there is insufficient personnel or inadequate physical space to implement effective dual-practitioner BVM ventilation. The introduction of a novel pedal-operated compressor device using a foot pedal as the bag compressor allows a single practitioner to administer consistent respiratory rates and tidal volumes that may be comparable with the dual-practitioner technique.

Our study demonstrated that, when compared with traditional single-practitioner BVM ventilation, the use of the pedal-operated compressor delivered higher mean tidal volumes and resulted in fewer out-of-range breaths when providing respiratory support in a simulated model. This was despite having minimal training (ie, 8 minutes) on how to use the pedal-operated compressor, and these results were consistent regardless of the user's prior experience with BVM ventilation. Furthermore, the tidal volumes achieved with the pedal-operated compressor approximated tidal volumes achieved with dual-practitioner techniques in other studies.^{8,22} In essence, the pedal-operated compressor may allow a single healthcare practitioner to achieve similar results as dual-practitioner BVM ventilation quickly and efficiently.

Furthermore, a secondary analysis to look at the absolute numbers of in-range or out-of-range breaths delivered demonstrated that the pedal-operated compressor had a significantly lower median number of out-of-range breaths. Subjectively, participants stated concern that using the strength and force generated by the foot to compress the bag may result in delivery of breaths with suprathreshold volumes and barotrauma. Our study demonstrated that this was not the case. There was no difference in the delivery of suprathreshold volumes between both devices. The majority of out-of-range breaths delivered by participants were attributed to low volumes. We suspect that this might have been related to having a compressor on the ground connected to ventilator tubing created a large amount of dead space that the foot must overcome.

TABLE 3 Subjective Feedback on Pedal-Operated Compressor

One thing I liked	One thing I did not like
"I was able to use a 2-handed technique with less fatigue."	"It would feel more comfortable if you could step/pedal with your toes similar to gas pedal"
"Two-hand technique allows for more reliable seal."	"I'm just not used to it yet, but I think with time I would become more facile."
"Ability to use 2 hands but not rely on a partner."	"Felt unsteady standing on 1 foot."
"Can do 2-hand hold, good for seal and small hands."	"Awkward to push down with my heel, kept hitting my knee on the stretcher."
"Better hand comfort."	"Must have space for floor apparatus and carry more equipment."
"Two-hand grip on mask."	"Its not always secure to the ground."
"Better chest rise because tighter seal."	"I had trouble coordinating my foot with the appropriate bag compression, but it seems comfortable to get comfortable with."
"It hurts my hands less than with bagging."	"It may be difficult for some to keep their foot elevated in between breaths."

Another compelling feature of the pedal-operated compressor is its ease of use. More than three-quarters of participants labeled the pedal-operated compressor as "easy" or "very easy" to use, despite only having had an 8-minute teaching session on how to use the device. Comparatively, fewer than half noted that the standard device was "easy" or "very easy" to use. Selected subjective, open-ended feedback regarding the pedal-operated compressor are noted in Table 3. Notably, if given the option to use 1 device in a real-life clinical scenario, the majority of participants preferred the use of the novel pedal-operated compressor.

An additional advantage of the pedal-operated compressor is the feasibility of building the device from inexpensive and readily available materials. They are found in most medical settings and can be replicated easily. The pedal-operated compressor can also be implemented with any existing model of self-inflating BVMs as well as with other standard ventilatory equipment. Thus, widely implementing the use of the pedal-operated compressor in the hospital setting could occur efficiently without the need to acquire additional supplies besides the pedal-operated compressor. The practicality of the pedal-operated compressor may be useful in different clinical scenarios. In settings where ventilators may be scarce or patients require manual ventilatory support for long periods of time (eg, low-resource settings or in the back of an ambulance), the use of the pedal-operated compressor may allow for healthcare practitioners to provide breaths for more time before feeling fatigued.

6 | CONCLUSIONS

The study findings demonstrated that the pedal-operated compressor is non-inferior to the standard BVM device when performing single-practitioner ventilatory support. The novel pedal-operated compressor has the potential to significantly improve patient care in the acute care setting by improving delivery of tidal volumes, producing a reduced amount of fatigue, and minimizing the number of healthcare practitioners required to deliver high-quality cardiopulmonary resuscitation. Future studies could aim to directly compare the pedal-operated compressor to dual-practitioner techniques to observe outcomes when improving ergonomics of the current device, measure the effects of sources of haptic feedback such as the addition of a manometer or a metronome, measure differences between specific ventilator parameters and pressures, and assess the efficacy of the pedal-operated compressor in vivo experimental settings.

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CONFLICT OF INTEREST

All authors have no conflicts of interest to disclose.

AUTHOR CONTRIBUTIONS

Sakina H. Sojar was one of the constructors/engineers of the pedal-operated device, conceptualized and designed the study, primarily drafted the manuscript, and reviewed and revised the manuscript. Zachary J. Neronha was one of the constructors/engineers of the pedal-operated device, assisted in conducting the study, and contributed to the drafting of the manuscript. Brian Vuong was one of the constructors/engineers of the pedal-operated device, assisted in conducting the study, was the primary extractor of data from the simulation software, and contributed to the drafting of the manuscript. Julia R. Puzone was the primary research assistant on the study,

recruited participants and conducted the study, and contributed to the drafting of the manuscript. Paul C. Decerbo contributed in engineering the device, assisted in conducting the study, and facilitated the proper use of the simulation software to conduct the study with our research assistant. Robyn Wing participated in study design, facilitated the study, and edited the manuscript for important intellectual content. She served as the primary investigator for this study. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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