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QUALITATIVE INVESTIGATION OF EMS PROVIDER EXPERIENCES WITH A FLOW-REGULATING SAFETY DEVICE FOR MANUAL VENTILATION: A PRELIMINARY REPORT

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ABSTRACT

Background: Over-ventilation during bag-valve-mask (BVM) ventilation (and manual ventilation in general) is a well-documented hazard in prehospital emergency care. It is associated with increased intrathoracic pressure, reduced cardiac output, gastric insufflation, and decreased survival in cardiac arrest and traumatic brain injury. The Sotair® (SafeBVM Corp., Boston, MA), is a flow-regulating safety device (FRSD) designed to prevent over-ventilation by limiting tidal volume during manual ventilation. Despite its potential clinical utility, provider-level experiences with the device in the real-world EMS clinical settings remain unreported.

Objective: We sought to explore experiences of EMS providers using the Sotair® device in clinical and training settings, with attention to perceived usability, clinical outcomes, barriers to consistent use, and recommendations for improvement.

Methods: Seven semi-structured interviews were conducted with EMS providers (EMTs, paramedics, training officers, and rescue chiefs) who have used the FRSD clinically. Interviews were analyzed using standard rapid thematic analysis. Thematic saturation was assessed iteratively and confirmed by convergence across all seven interviews.

Results: Six themes emerged: (1) Device Understanding and Simplicity: all participants described the device as intuitive, and required minimal training; (2) Training Value: the device demonstrated unexpected utility as a training instrument, with novice providers who trained with the device outperformed experienced peers on a ventilation feedback platform, with retained technique after device removal; (3) Clinical Experiences: primary use was cardiac arrest; participants reported anecdotal improvements in ROSC rates and reductions in gastric insufflation; (4) Cognitive Load Reduction and Anxiety Management: participants described reduced mental burden during resuscitation, freeing attention for scene management; (5) Barriers to Consistent Use: forgetting to deploy the device, resistance from experienced providers, cost concerns, and uncertainty in specific clinical scenarios (head trauma, drowning, pediatric patients) were identified; (6) Recommendations: pre-integration with BVM was endorsed by all participants; additional recommendations included a pediatric version, peer-to-peer marketing, and usage tracking research.

Conclusions: EMS providers reported favorable experiences with the FRSD across clinical and training contexts. The device's simplicity, cognitive load benefits, and emergent value as a training tool suggests both direct clinical and educational applications. Barriers to adoption, most notably forgetting to deploy, may be addressable through pre-implementation with standard BVM equipment.

INTRODUCTION

Manual ventilation is a mainstay of prehospital emergency care. It is universally taught and utilized by all emergency medical services (EMS) systems, with guidance from the National Association of EMS Physicians (NAEMSP) and the American Heart Association (Carlson et al., 2022; Kleinman et al., 2025; Lyng et al., 2022). Manual ventilation is most commonly utilized with a bag-valve-mask configuration using a self-inflating bag, but it is also used when an advanced airway (endotracheal tube or supraglottic airway) has been placed. Unlike mechanical ventilation (with tightly controlled ventilatory parameters), manual ventilation is a skill that is heavily operator-dependent and often results in inappropriate ventilation being delivered.

Manual ventilation is also fraught with a variety of potentially injurious clinical and pathophysiologic conditions. These include hypoventilation, hyperventilation, barotrauma resulting in pneumothorax and/or pneumomediastinum (both of which can affect hemodynamics), gastric insufflation and aspiration, and downstream inflammation-driven lung injury. These can result in manual ventilation induced lung injury (White et al., 2024).

The NAEMSP Position Statement states: All EMS clinicians must be proficient in bag-valve-mask ventilation. EMS clinicians should use available techniques and adjuncts to achieve optimal mask seal, improve airway patency, optimize delivery of the correct rate, tidal volume, and pressure during manual ventilation, and allow continual assessment of manual ventilation effectiveness (Lyng et al., 2022). Several adjuncts for manual ventilation have been cleared by the Food and Drug Administration (FDA). Most provide visual feedback on tidal volume and peak inspiratory pressure, as well as respiratory rate. These devices have largely been studied in simulation settings (Smyth et al., 2025).

One of these FDA-cleared devices, the Sotair® (Safe BVM, Corp, Boston, MA), is a flow-regulating safety device (FRSD) for use during manual ventilation. When inspiratory pressure exceeds 55 LPM the device triggers an immediate stoppage of flow, alerting the provider that inspiratory flow, and thereby pressure, have exceeded safe limits. The feedback is tactile and auditory, rather than visual. We conducted a qualitative study of prehospital end-users of this FRSD, all of whom had used it clinically on patients.

METHODS

This study was approved by the University of Pittsburgh Institutional Review Board. We used a qualitative rapid thematic analysis design, appropriate for applied healthcare settings requiring timely, evidence-informed findings. Semi-structured interviews were conducted to allow for standardized coverage of topics, while holding space for emergent, inductive themes.

We identified three EMS agencies who were willing to participate and had been using the FRSD in their agency for at least one year. Recruitment was conducted via email distribution of a poster explaining the purposes of the study. Distribution was done through each EMS agency's Medical Director. It was made clear that the interviews would be audio-recorded for later transcription, but participation would be kept entirely anonymous. Participants must have had direct clinical experience with the FRSD. Recruitment was constrained by the occupational demands of prehospital providers, which

is common in research with this population (Leonard et al., 2012; Newington & Metcalfe, 2024). Yet, a sample of seven was deemed sufficient given the study's narrow, homogeneous population. All participants shared professional training, scope of practice, and direct clinical experience with the device. Thematic saturation was assessed iteratively, as no new themes emerged in subsequent interviews, confirming adequate informational power consistent with established qualitative standards (Guest et al., 2006; Malterud et al, 2016). Participants were paid 100 USD by prepaid card for completing the study.

Interviews were conducted by a study author, who is a qualitative methodologist at the University of Pittsburgh's Center for Biostatistics and Qualitative Methodology (CBQM), with no affiliation to the Sotair® manufacturer. Interviews were conducted remotely via video conference using Microsoft Teams. The interviews were conducted individually (i.e., one subject at a time) and audio-recorded with participant consent and lasted approximately 30 minutes. An interview summary template was designed using the research questions and the emerging themes from the interviews. The interviewer then listened to the interviews and summarized them using the template; this process was repeated to assure no relevant data were missed. A semi-structured interview guide explored participants' understanding of the device, device-related training experiences, clinical use, perceived benefits, barriers to use, and recommendations.

Transcripts were analyzed using rapid (Nevedal et al., 2021) thematic analysis, adapting Braun and Clarke's reflexive thematic analysis approach for applied research contexts (Braun & Clarke, 2021). Analysis transpired through the iterative review of the interview summaries to generate themes and sub-themes. Themes were reviewed against the full dataset, refined, and named. Illustration quotes were selected to represent each theme. The analyst maintained a reflectivity journal to document analytic decisions. All six themes emerged across all seven interviews.

RESULTS

Seven EMS providers were recruited from the three EMS agencies that had voluntarily agreed to participate. Participants included EMTs, paramedics, training officers, and a rescue chief, representing a range of organizational roles, agency sizes, and device exposure (Table 1).

Participant Number	EMS Role	Sotair® Field Uses	Primary Use	Secondary Uses
P1	Educator/Provider	4-5	Cardiac Arrest	Unresponsive patients with pulses
P2	Deputy Chief of EMS	3	Cardiac Arrest	None Mentioned
P3	Rescue Chief	1	Cardiac Arrest	Respiratory arrest, opioid overdoses, compromised respiratory drive
P4	Firefighter EMT	10+	Cardiac Arrest	CHF, sepsis, assisted ventilation
P5	Firefighter EMT	3	Cardiac Arrest	None Mentioned
P6	Paramedic/Training Officer	2	Assisted Ventilation	Unresponsive patients with pulses
P7	Paramedic	12-14	Cardiac Arrest	Unresponsive patients with pulses

Table 1. Self-reported EMS roles, number of field uses, and clinical uses of the Sotair® device by the seven participants.

Theme 1: Device Understanding and Simplicity

All participants demonstrated understanding of the FRSD, describing it as a flow-rate restrictor that limits inspiratory tidal volume when the provider squeezes the BMV too hard or too rapidly. Language used to describe this varied among participants. Perceived simplicity was the most recurring strength of the device endorsed by participants. Multiple participants stated that minimal training (e.g., brief explanation) was sufficient to use the device. While one participant suggested that even people without a medical background could use the device, another disagreed, saying it would take at least some medical training.

Theme 2: Training Experiences and the Device as Training Tool

Across departments, training included either a short instructional video or a video combined with hands-on, mannequin-based practice. All participants considered their current training adequate for device use. An emergent, recurring finding was the device's value as a training instrument beyond its clinical application. Among the participants, one shared how the novice providers (e.g., EMRs and firefighters with minimal bagging experience) trained with FRSD outperformed experienced peers on a ventilation feedback platform (Sotair IQ®, SafeBVM, Boston, MA). It was also reported that when the device was subsequently removed, novice providers maintained their improved ventilation technique, demonstrating skill acquisition via the FRSD exposure. A training gap that was mentioned was the mismatch between short training sessions lasting a few minutes and real-world experiences, where they might need to sustain ventilation for as much as 20 to 30 minutes.

Theme 3: Clinical Experiences

Cardiac arrest was the primary clinical context for Sotair use, as mentioned by all participants. Other uses included respiratory arrest, opioid overdose, and unresponsive patients. According to participants' experiences, reported clinical outcomes were favorable. A participant reported improvement in return of spontaneous circulation (ROSC) rates since department-wide adoption. Another described reduced gastric insufflation as observed through decreased suctioning of gastric contents. A third described smooth performance during an intubation scenario with unimpeded chest rise. Two participants identified challenging scenarios. One experienced frustration during a 30-minute transport resulting in hand fatigue when the FRSD repeatedly triggered. Another encountered a complex CHF/sepsis case with "stiff lungs" and was unsure if the device added to the difficulties experienced. Despite these cases, both participants maintained overall positive assessments of the device. A training officer described a first responder on their first cardiac arrest receiving real-time corrective feedback through the device's mechanism, demonstrating the utility for novice users.

Theme 4: Cognitive Load Reduction and Anxiety Management

A prominent, cross-cutting, and emergent theme was the reduction of cognitive load and anxiety. Multiple participants described how the device frees mental resources during a resuscitation. One participant framed this as giving providers "freedom of the mind to operate on the scene." Others reported how the device turned the ventilation task from a conscious, effortful task to a more automatic one. A training officer noted additional

benefits such as being able to delegate bagging to less experienced personnel more confidently. Differently, a participant mentioned how anxiety heightens when the restrictor activates unexpectedly, followed by reduced anxiety once the provider adjusts and gains confidence in improved technique. Another framed the device's effects as providing real-time confirmation of correct performance, fostering confidence rather than simply reducing anxiety.

Theme 5: Barriers to Consistent Use

Four barriers were identified. First and most prominent was forgetting to deploy the device. Every department reporting consistent use had independently adopted the workaround of preloading the FRSD onto BVMs during restocking. Second, resistance from experienced providers was documented across interviews. While this was mostly reported as an observation from participants working with more experienced co-workers, in one account, a paramedic with approximately 20 years of experience became frustrated with the device's restrictions, demanded its removal, and refused to use it. Third, cost was raised as a barrier by various participants. At approximately $20 per single-use device, cost was perceived as a meaningful barrier for high-volume services, though all participants indicated it would not lead them to discontinue its use. Fourth, clinical uncertainty was noted regarding head trauma (where ventilation may be indicated), drowning and pulmonary edema (where higher airflow may be needed), aspiration risk (regarding the valve trapping vomitus), and pediatric patients (no approved pediatric version currently exists).

Theme 6: Recommendations for Improvement

Pre-integration of the FRSD with BVM equipment was endorsed by all participants. Every department with consistent use had independently preloaded the device; participants recommended this be either built into the product design or at a minimum explicitly advised in training or sales material. Additional recommendations included: development of peer-to-peer testimonials from early-adopting departments, which were predicted to be more persuasive to resistant colleagues than clinical studies; systematic research on actual deployment rates to capture compliance gaps; and deployment of a pediatric sized version, given that pediatric emergencies generate heightened anxiety and that over-ventilation risks may be equal or more critical in that population.

DISCUSSION/LIMITATIONS

This preliminary report identified six themes regarding the clinical use of the FRSD. The functionality of the device appears to be well comprehended, training requirements appear to be minimal, and the device is reportedly somewhat easy to use. These findings are similar to other manual ventilation safety adjuncts and thus were not unexpected. The primary barrier to its use is forgetting to deploy it.

While the study is limited by its small number of participants, it is remarkable that thematic saturation was achieved just the same. The study is also limited in that actual clinical performance of the FRSD was not evaluated (effects on ROSC rates, gastric insufflation, etc.). The study does provide some valuable insights into what future questions remain unanswered.

CONCLUSION

EMS providers reported consistently favorable experiences with the FRSD across clinical and training contexts. The device's simplicity and cognitive load benefits support its clinical utility, while its emergent value as a training instrument – producing durable ventilation skill in novice providers – warrants recognition as a secondary application. The primary barrier to consistent deployment, forgetting to attach the device under emergency conditions, appears addressable through pre-integration with standard BVM equipment. Prospective research measuring objective ventilation parameters and patient-level outcomes is needed to confirm these preliminary findings.

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