Manual volume delivery via Frova Intubating Introducer: a bench research study

Administration manuelle d'un volume d'air au moyen de l'introducteur pour intubation Frova: projet de recherche en laboratoire

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Abstract

Purpose Oxygen delivery through a Frova Intubating Introducer may be life-saving, and gas flow characteristics through this device have been described. Nevertheless, the feasibility of using a self-inflating resuscitation bag to deliver air or oxygen through this device has not been assessed. We compared volumes of air delivered and peak pressures generated with normal and maximal bimanual compression of a self-inflating resuscitation bag connected to a 70 cm Frova Intubating Introducer.

Methods In this bench research study, the proximal end of the 14-F Frova Intubating Introducer was connected to the self-inflating resuscitation bag, and the distal end was connected to a flow analyzer fitted with an adult test lung. Thirty-five anesthesia health care providers (staff/trainees) squeezed the self-inflating resuscitation bag with three normal and three maximal bimanual compressions.

Endpoints of interest included the delivered volume of air and generated peak pressure.

Results Normal bimanual compression resulted in a smaller mean (standard deviation) volume of air and peak pressure compared with maximal bimanual compression [554 (131) vs 955 mL (121); mean difference – 400.4; 95% confidence interval [CI], – 441.8 to – 359.0; $P < 0.001$; and 22.0 (3.4) vs 41.8 cmH₂O (13.3); mean difference – 19.7; 95% CI, – 23.5 to – 15.9; $P < 0.001$, respectively].

Conclusion Clinically useful, life-sustaining volumes of air can be delivered using normal and maximal bimanual compression of a self-inflating resuscitation bag connected to a 70 cm Frova Intubating Introducer.

Trial registration www.clinicaltrials.gov (NCT0278 6355); registered 27 January, 2016.

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Résumé

Objectif L'administration d'oxygène au travers d'un introducteur (bougie) Frova pour intubation peut sauver une vie et les caractéristiques du débit de gaz à travers ce dispositif ont été décrites précédemment. Néanmoins, la faisabilité de l'utilisation d'un ballon de réanimation pour administrer de l'air ou de l'oxygène à travers ce dispositif n'a pas été évaluée. Nous avons comparé des volumes d'air délivrés et les pressions maximales générées avec une compression bimanuelle normale ou maximale d'un ballon de réanimation autogonflant relié à un introducteur Frova pour intubation de 70 cm.

Méthodes Dans cette étude expérimentale, l'extrémité proximale de l'introducteur Frova 14F pour intubation a été connectée au ballon de réanimation autogonflant et son extrémité distale a été connectée à un analyseur de débit

adapté à un poumon adulte artificiel. Trente-cinq prestataires d'anesthésie (patrons/résidents) ont comprimé le ballon de réanimation avec trois compressions bimanuelles normales et trois compressions maximum. Les critères d'évaluation ont inclus le volume d'air délivré et la pression maximum générée.

Résultats La compression bimanuelle normale a fourni un volume d'air moyen (ET) et une pression maximum moyenne (ET) inférieurs à la compression bimanuelle maximum (554 [131] contre 955 mL [121]; différence des moyennes, -400,4; intervalle de confiance [IC] à 95 % : -441,8 à -359,0; $P < 0,001$; et 22,0 [3,4] contre 41,8 cmH₂O [13,3]; différence des moyennes, -19,7; IC à 95 % : -23,5 à -15,9; $P < 0,001$).

Conclusion Des volumes d'air cliniquement utiles pour le maintien en vie peuvent être administrés par compression bimanuelle normale et maximum d'un ballon de réanimation autogonflant connecté à un introducteur Frova pour réanimation de 70 cm.

Enregistrement de l'essai clinique www.ClinicalTrials.gov (NCT02786355); enregistré le 27 janvier 2016.

Difficult airway algorithms indicate that a surgical cricothyroidotomy may be a necessary rescue manoeuvre in a “can't intubate, can't oxygenate” scenario.¹⁻³ When performing a cricothyroidotomy, passage of the endotracheal tube through a front-of-neck access using a previously inserted introducer as a guide may be mechanically impeded because of the larger diameter of adult-sized endotracheal tubes compared with the introducer. In this critical situation, it has been advocated that a patient be re-oxygenated by connecting the introducer to an anesthetic circuit.⁴

The 70 cm 14-Fr Frova Intubating Introducer (Frova Introducer) is a commonly utilized device to facilitate endotracheal intubation; it is hollow with an internal diameter of 3.0 mm and has two small orifices (0.5 cm and 1 cm) at its distal end (Fig. 1). Gas flow characteristics through the Frova Introducer using constant driving pressures have been studied.⁵ Nevertheless, no study has examined gas flow through the Frova Introducer using bimanual compressions of a self-inflating resuscitation bag.

In this study, we measured airflow parameters produced by bimanual compressions of the self-inflating resuscitation bag attached to the Frova Introducer. The primary endpoint

was to determine volumes of air delivered and peak pressures generated using the 70 cm 14-Fr Frova Introducer during normal and maximal bimanual compression of the self-inflating resuscitation bag. The secondary endpoints were to correlate participants' glove size to the volumes of air delivered and peak pressures that were generated.

Methods

This crossover study was registered at ClinicalTrials.gov (NCT02786355). Data were collected at the British Columbia Women's Hospital and Health Centre, University of British Columbia, Vancouver, Canada. This study received ethics board approval from the University of British Columbia Children's and Women's Research Ethics Board on 1 February 2016 (H15-03391) and signed informed consent was obtained from all participants. Study participants included anesthesia staff, fellows, and residents working at either the British Columbia Children's or Women's Hospitals. Inclusion criteria comprised active involvement in providing anesthesia care in a critical care environment, and the ability to manually compress a self-inflating resuscitation bag. No restrictions were placed on the number of years of anesthesia training.

The proximal end of the 70 cm 14-Fr Frova Intubating Introducer (Cook Medical, Bloomington, IN, USA) was connected via a Rapi-Fit® Adaptor (Cook Medical, Bloomington, IN, USA) to the self-inflating resuscitation bag (Ambu® SPUR® II Single Patient Use Resuscitator, Ballerup, Denmark). The Frova Intubating Introducer comes with two adaptors, a luer lock connector, and a 15 mm connector. The latter facilitates the connection of the Frova Introducer to a ventilator device. The distal end of the Frova Introducer was fitted, using a piece of rubber as a sealant, to a standard 15 mm universal connector attached to a FlowAnalyser PF-300 (IMT Medical, Buchs, Switzerland). In turn, the FlowAnalyser PF-300 was attached to a B&B Adult Test Lung™ (B&B Medical Technologies, Carlsbad, CA, USA; compliance of 26 mL/cmH₂O at 600 mL tidal volume; Fig. 2). The self-inflating resuscitation bag was filled with room air and no supplemental oxygen was provided. The FlowAnalyser PF-300 was calibrated before each data collection session. An unblinded research assistant recorded the volume of air delivered, peak pressure generated, and inspiratory time.

Fig. 1 The 70 cm Frova Intubating Introducer and Rapi-Fit® Adaptor

Fig. 2 Experimental set-up

Participants' surgical glove size and anesthesia experience were recorded.

The study design consisted of two maneuvers: "normal" and "maximal" effort bimanual compression of the self-inflating resuscitation bag attached to the 70 cm Frova Introducer. "Normal" bimanual compression was defined as the effort required to gently squeeze the self-inflating resuscitation bag with both hands until the fingers and thumbs met, thus simulating routine tidal volume delivery with such a device. "Maximal" bimanual compression was defined as the maximum effort one could generate by squeezing the self-inflating resuscitation bag with both hands. Participants were assessed on three attempts for each effort of manual volume delivery. Prior to data collection, participants were given three practice attempts at squeezing the self-inflating resuscitation bag with normal and maximal bimanual compressions.

A convenience sample of 35 participants was chosen for this study, based on the anticipated number of anesthesia healthcare providers at BC Children's and Women's Hospitals who would be available to participate.

Table 1 Participants' level of anesthesia training

Clinician rank	Number of participants	Percent of participants
Staff	19	54%
Fellow	4	11%
Resident	12	34%

Statistical analyses were carried out using R v3.4.3 (R Core Team 2017, Vienna, Austria). We compared the volume of air (mL) delivered and the peak pressure (cmH₂O) generated with normal versus maximal bimanual compressions using paired-samples *t* tests. We examined the relationship between glove size, volume of air, and peak pressure for both normal and maximal bimanual compression separately using robust linear regression. Robust linear regression is an extension of ordinary least-squares regression that minimizes the effects of outliers on the estimate of the regression line by down-weighting cases with large residuals.⁶ In this study, robust linear regression suggests that for every increase in one glove size the average volume of air delivered or peak pressure generated increases by the corresponding regression coefficient, beta (β).

Results

Thirty-five participants with varying levels of anesthesia experience were recruited (Table 1). Normal bag compression produced a mean (standard deviation; SD) of 554 (131) mL of delivered air, while maximal compression delivered 955 (121) mL; mean difference, -400.4 ; 95% confidence interval [CI], -441.8 to -359.0 ; $P < 0.001$; Table 2. These volumes generated mean (SD) peak airway pressures of 22.0 (3.4) and 41.8

Table 2 Volumes of air delivered, peak pressures generated, and inspiratory times with normal- and maximal-effort bimanual compression

	Normal bimanual compression	Maximal bimanual compression	<i>P</i> value	Difference in means (95% confidence interval)
Volumes of air delivered (mL), mean (SD)	554 (131)	955 (121)	< 0.001	-400.4 (-441.8 to -359.0)
Peak pressures generated (cmH ₂ O), mean (SD)	22.0 (3.4)	41.8 (13.3)	< 0.001	-19.7 (-23.5 to -15.9)
Inspiratory times (sec), mean (SD)	3.3 (1.1)	2.9 (0.74)	0.08	0.43 (-0.06 to 0.91)

SD = standard deviation

Fig. 3 Relationship between the delivered volumes of air (mL) and glove size, as measured during normal and maximal bimanual resuscitation bag compression. Each symbol represents an individual measurement, and the lines indicate the best fit using robust regression analysis

(13.3) cmH₂O, respectively (mean difference, -19.7 ; 95% CI, -23.5 to -15.9 ; $P < 0.001$; Table 2). Mean (SD) inspiratory times for both types of bag compression were similar [3.3 (1.1) vs 2.9 (0.74) sec; mean difference 0.43; 95% CI, -0.06 to 0.91; $P = 0.08$; Table 2]. A direct correlation was observed between glove size and volume of air for normal compression ($\beta = 83.2$, standard error [SE] = 29.9, $P = 0.009$) and maximum compression ($\beta = 81.2$, SE = 26.1, $P = 0.004$; Fig. 3). With maximum compression, a direct correlation was also observed between glove size and peak pressure ($\beta = 8.7$, SE = 2.8, $P = 0.004$), but no relationship was observed with normal compression ($\beta = 0.7$, SE = 0.7, $P = 0.30$; Fig. 4).

Discussion

We demonstrated that normal bimanual compression of a self-inflating resuscitation bag connected to the 70 cm Frova Introducer produced a tidal volume of approximately 550 mL of air over 3.3 sec with a mean peak pressure of 22.0 cmH₂O. In comparison, maximal bimanual compression produced almost double the volume and peak airway pressure over a similar inspiratory period. Glove size was directly correlated with volume of air delivered during normal and maximal bag compression and with peak pressure generated during maximal bag compression. Our findings are consistent with the results of a previous study of manual ventilation through intravenous and minitracheotomy catheters.⁷ In that study, investigators found that approximately 900 mL of oxygen could be delivered through a minitracheotomy catheter with an internal diameter of 3.3 mm and a length

Fig. 4 Relationship between the generated peak pressures (cmH₂O) and glove size, as measured during normal and maximal bimanual resuscitation bag compression. Each symbol represents an individual measurement, and lines indicate the best fit using robust regression analysis

of 4.9 cm when using maximal bimanual compression. In our study using the Frova Introducer, with an internal diameter of 3.0 mm and a length of 70 cm, similar volumes were observed with maximal bimanual compression.

As previously advocated by Heard *et al.*,⁴ during an airway crisis situation, it may be possible to improve or adequately oxygenate a patient through the Frova Introducer prior to establishing a more secure airway (e.g., cricothyroidotomy). Moreover, if an anesthetic circuit is available, it can be attached to the Frova Introducer and tracheal position confirmed via capnography.⁴ Similarly, the Frova Introducer can be considered to be a temporizing solution in severely hypoxemic patients who would require a surgical airway, but in whom this option is delayed or not readily available.

Our study demonstrated that clinically relevant volumes of air can be delivered through the 70 cm 14-Fr Frova Introducer using bimanual compression of a self-inflating resuscitation bag. The mean volumes of air delivered by both normal and maximal bimanual compression were sufficient to meet the recommended tidal volume of 6 mL·kg⁻¹ of predicted body weight in an adult patient,^{8,9} albeit over a longer inspiratory time. Although maximal bimanual compression was associated with 400 mL of additional volume, it also resulted in higher peak airway pressures. This may cause lung damage as the mean volume of air delivered and peak pressure generated surpassed 700 mL and 30 cmH₂O, respectively. These two thresholds have been previously identified as risk factors for acute respiratory distress syndrome.¹⁰ Oxygenation through the Frova Introducer can pose challenges. For example, oxygenation can be compromised in patients as air or oxygen delivered via the Frova Introducer may

escape from the nose or mouth. The risk of barotrauma requires consideration in situations of upper airway obstruction. In a related manner, “breath stacking” and barotrauma may occur if insufficient time is given for the lungs to empty during the expiratory cycle. One possible solution to mitigate this risk is to utilize a Ventrain® (Ventinova Medical, Maastricht, Netherlands) in combination with the Frova Introducer. A Ventrain® allows active inspiration and expiration through a narrow bore tube when using a high-pressure continuous oxygen source (6–15 L·min⁻¹ flow).^{11,12}

This bench research study has several limitations. To conduct the study, we employed the B&B Adult Test LungTM that is routinely used at our hospital to test anesthetic machines. The reported compliance of this lung simulator, 26 mL/cmH₂O at 600 mL tidal volume, is less than the normal adult lung compliance (60–100 mL/cmH₂O).¹³ Thus, extrapolation of these findings to an actual clinical situation may be uncertain. Also, we measured volumes and peak “airway” pressures using room air rather than an oxygen-air mixture, which would be the case when managing patients, particularly during a crisis airway scenario. This could have some influence on measured volumes and pressures because of differences in gas densities. We did not investigate the capacity of Frova Introducers to allow for expiration, and this may be particularly important if “breath stacking” is to be avoided at higher rates of ventilation. Although not relevant to this study, we would caution that over-enthusiastic passage of the Frova introducer beyond the carina could cause distal airway trauma, including bronchus rupture and pneumothorax.

In conclusion, in this bench research study, we showed that clinically relevant volumes of air can be delivered via a 70 cm 14-Fr Frova Intubating Introducer with bimanual compression of a self-inflating resuscitation bag. This may be clinically useful in critical airway management situations.

Conflicts of interest None declared.

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Author contributions Preeti Dewan helped design and conduct the study and write the manuscript. James Taylor helped analyze and interpret the data and write the manuscript. Vit Gunka helped conduct the study and write the manuscript. Arianne Albert helped design the

study, analyze the results, and write the manuscript. Simon Massey helped conceive the study, design the study, conduct the study, review the analysis, and write the manuscript.

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