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Effect of a Speaking Valve on Nasal Airflow During Tracheostomy Weaning: A Case Series

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In the intensive care unit (ICU), many patients with acquired brain injury (ABI) benefit from tracheostomy [1]. Tracheostomy weaning protocols typically include cuff deflation and tube capping [2-4]. However, the roles and importance of these steps are debated. The rationale behind tube capping is to recreate airflow through the upper airway that promotes laryngeal reafferentiation, natural heating, air filtration, humidification through the nose, swallowing, and improved subglottic pressure [5, 6] (Fig. 1). However, tube capping can increase the respiratory workload by reducing the tracheal lumen diameter because it forces the airflow around the cannula [7] (Fig. 1, step 2 and b). Therefore, this may be considered risky or too demanding [7]. Cuff deflation without tube capping is sometimes suggested instead of cuff deflation with tube capping [8], but it has not been proven that this sufficiently recreates the upper airway airflow necessary for tracheostomy weaning.

The objective of this study was to describe and compare the upper airway airflow, swallowing, and signs of increased respiratory workload under the following conditions: cuff deflation alone and cuff deflation with a speaking valve. To our knowledge, this comparison is novel.

This is a prospective case series (ClinicalTrials.gov NCT03512054) approved by ethics committee (Approval No. 17-12-08).

The inclusion criteria were age \geq 18 years, hospitalization with ABI, tracheostomy performed in the ICU, weaned from mechanical ventilation (MV), scheduled for

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tracheostomy weaning, written informed consent from the patient or a legal representative, and patient access to the benefits of the French health care system.

The exclusion criterion was severe malnutrition defined as follows: body mass index < 16 kg/m² or albuminemia < 20 g/L for patients aged < 70 years; body mass index < 18 kg/m² or albuminemia < 30 g/L for patients aged > 70 years.

All patients underwent tracheostomy weaning following a five-step logigram: step 0, deflation of the tracheostomy cuff; step 1, brief manual occlusion of the cannula (a few seconds, 1 min maximum) to assess airway patency before speaking valve placement; step 2, placement of a speaking valve for a full 12 h; step 3, capping the cannula with a plug for a full 24 h; and step 4, decannulation (see Gallice et al. [9] for a full description of the protocol).

We compared the status of nasal airflow, swallowing, and the use of accessory respiratory muscles at step 0 (deflated cuff alone), the beginning of step 2 (deflated cuff with placement of a speaking valve), and 1 h after step 2. For each patient, we used polygraphy to continuously record the nasal respiratory flows (inspiratory and expiratory) and thoracic and abdominal movements during the first 2 h of tracheostomy weaning. Over this period, we expected that patients would complete steps 0 and 1 and that step 2 would commence and last at least 1 h after the start of the weaning process. We used a ResMed Nox Polygraph (PG) (San Diego, CA). We recorded nasal airflow using a nasal cannula. Each recording was obtained with the mouth closed to avoid signal loss associated with mouth breathing. We recorded thoracic and abdominal movements using thoracic and abdominal straps (Fig. 1, lower panel). We evaluated breathing status based on the movements of the abdominal and thoracic straps shown on the PG recording. Data were extracted from the PG

(See figure on next page.)

Fig. 1 Upper panel: Tracheostomy with an inflated cuff. Airflow is possible only through the cannula (solid lines). Step 0, Airflow with a deflated cuff alone; solid lines: principal airflow routes (inspiratory and expiratory airflows through the cannula). Step 2, Airflow with a deflated cuff and a speaking valve; solid lines: the principal airflow routes (inspiratory airflow through the cannula, expiratory airflow through the nose); dashed lines: accessory airflow route (inspiratory airflow through the nose). Intermediate panel: An enlarged view of a tracheostomy tube inserted in the trachea. **a** The function of a speaking valve during inspiration; solid line, inspiratory airflow does through the cannula; dashed line, accessory inspiratory airflow through the upper airway. **b** The function of a speaking valve during expiratory airflow closes the valve and the air is then forced to pass through the upper airway. Lower panel: Example polygraph traces (patient 10): upper graph, nasal airflow; intermediate graph, respiratory inductance plethysmographic flow (RIP), and thus the reconstituted respiratory flow is based on the thoracic and abdominal movements; lower graph, the thoracic and abdominal movements. Step 0, Recording with a deflated cuff alone. Step 2, Recording with a deflated cuff and a speaking valve placement. ant, anterior, RL, recording length (90 min), sup, superior

and anonymized in.edf format using ResMed Noxturnal software. Three stages of the entire recording were analyzed: step 0, the beginning of step 2, and 1 h thereafter if the patient remained in this step (step 2 plus 1 h) (Fig. 1, lower panel). Cuff deflation and the use of a speaking valve can cause intense coughing, which may affect the quality of data recording. Therefore, for each patient, we selected a clean sample of 5 min for each period for analysis. If it was impossible to obtain a clean 5-min sample, we selected a clean sample of the maximum possible duration. The data-processing module was specifically developed (by one of the authors, DC) for this study using the Xojo 2018 Release 2 computer-based tool integrated with signal display PGS-OSX software.

Activation of accessory inspiratory muscles (qualitative results: yes or no) at step 0 and step 2 was clinically observed and recorded by the physiotherapist who was implementing the protocol. These data served as indirect assessments of respiratory workload.

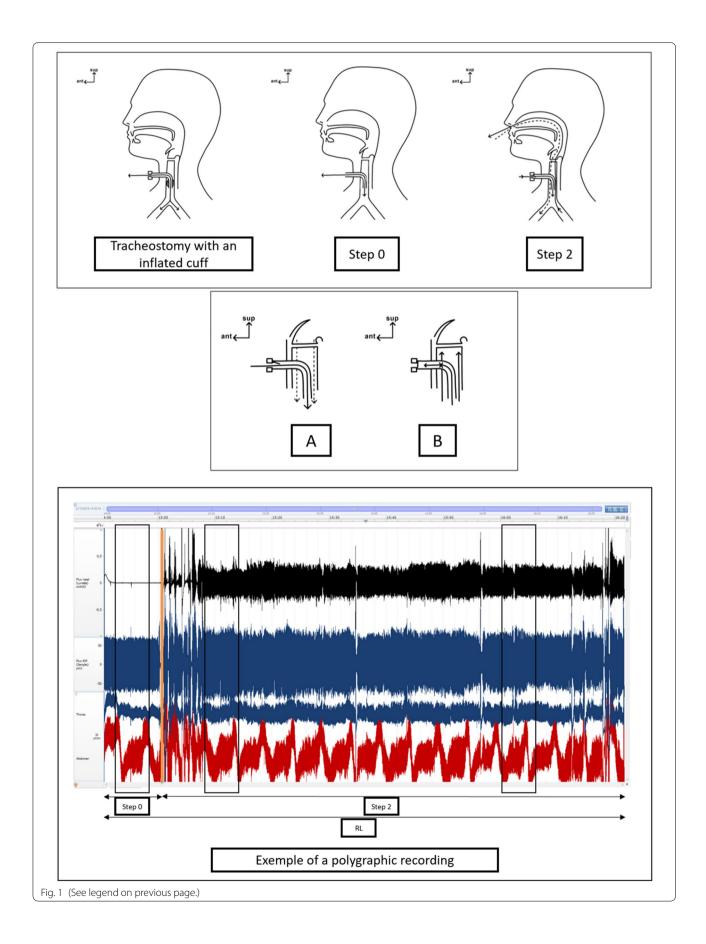
The numbers of spontaneous swallows were recorded at step 0 and step 2. A swallow was defined as a complete elevation of the larynx observed by the physiotherapist implementing the protocol. Observations were made during the first 5 min of steps 0 and 2. We also collected data on age, sex, tracheostomy model, Coma Recovery Scale revised score at inclusion, type of ABI, ICU length of stay, MV duration, time from intubation to tracheostomy weaning, functional status at ICU discharge, and lesion location (supratentorial, infratentorial, or both).

Statistical analysis employed SAS software (version 9.4; Cary, NC), with the two-sided type I error rate set to 0.05. The baseline quantitative patient characteristics are presented as numbers with means and standard deviations (SDs), or as medians with interquartile ranges

(IQRs). Nasal airflows are given as means with SDs or as medians with minimum and maximum values. Given the characteristics of the sensor, the airflows were estimated using the pressures recorded by the nasal cannula and are thus expressed in cmH₂O. Airflows were compared between steps 0 and 2, steps 0 and 2 plus 1 h, and steps 2 and 2 plus 1 h using the Wilcoxon signed-rank test. The numbers of swallows at steps 0 and 2 were compared in the same manner.

Our results were as follows: after discharge from neurological or traumatic ICUs to two neurosurgery units, all of 15 patients (10 women) were consecutively and exhaustively enrolled from 27/05/2019 to 21/12/2019. Three patients (patients 4, 8, and 15) failed to pass step 1 (manual tube occlusion with a deflated cuff) or did not tolerate the procedure. They exhibited airway patency impairments incompatible with appropriate analysis of nasal airflow. Therefore, they were excluded from statistical analysis. One patient passed step 2 but failed to continue to step 2 plus 1 h (patient 14). For the 12 patients included in analysis, the median age was 53 years (IQR 40-60 years); the median Coma Recovery Scale revised was 18 (IQR 13-21); the mean time from intubation to tracheostomy weaning was 57 days (SD 26 days); the mean ICU length of stay was 41 days (SD 15 days); and the mean MV duration 28 h (SD 10 h). Eight patients had supratentorial lesions, five had infratentorial lesions, and two had both (Table 1).

All patients had been tracheostomized in the ICUs using a percutaneous technique. We used the following tracheostomy tubes: Rusch size 8.5 for ten patients (internal diameter [ID] 8.7 mm, outer diameter [OD] 10.3 mm), Rusch size 10 for two patients (ID 10.2 mm, OD 12.3 mm), and Shiley 6LPC for three patients (ID



Patient	Age	Sex		CRS-r ICULOS (d) MV dur tior	MV dura- tion (d)	Time from intu- bation to TW (d)	Type of ABI	Functional status at ICU discharge TW protocol	TW protocol	Model of trache- ostomy
-	32	Σ	23	43	40	62	Fourth ventricle hemangioblastoma	mRS 4, cerebellar ataxia	Passed	Rusch 10
2	52	Σ	17	41	36	48	SAH (basilar trunk aneurysm)	mRS 5	Passed	Rusch 10
m	70	Σ	22	30	27	64	Left pontocerebellar angle meningioma	mRS 5, right hemiplegia	Passed	Shiley 6LPC
4	36	ш	19	30	16	38	ICH, SAH (left sylvian aneurysm)	mRS 5, right hemiplegia	Failed at step 1	Shiley 6LPC
5	47	ш	m	20	13	26	SAH (right internal carotid aneurysm)	mRS 5, left hemiplegia	Passed	Rusch 8.5
9	56	ш	22	40	27	50	Severe TBI	mRS 4, left hemiplegia	Passed	Rusch 8.5
7	32	Σ	9	62	38	85	SAH (right sylvian aneurysm)	mRS 5	Passed	Rusch 8.5
00	65	ш	23	36	26	56	SAH (anterior communicating artery aneurysm) mRS 4, right hemiplegia	mRS 4, right hemiplegia	Failed at step 1	Rusch 8.5
6	27	ш	20	74	38	115	Left ICH	mRS 5	Passed	Rusch 8.5
10	63	ш	18	38	11	50	SAH (right sylvian aneurysm)	mRS 5, left hemiplegia	Passed	Rusch 8.5
11	61	ш	16	38	36	47	SAH (right internal carotid aneurysm)	mRS 5	Passed	Rusch 8.5
12	46	щ	19	34	28	62	Posterior fossa astrocytoma	mRS 5, left hemiplegia	Passed	Shiley 6LPC
13	59	ш	14	47	26	56	SAH (pericallosa artery aneurysm)	mRS 5	Passed	Rusch 8.5
14	53	ш	12	22	17	23	SAH (right internal carotid aneurysm)	mRS 5, left hemiplegia	Failed at step 2 + 1 h	Rusch 8.5
15	40	Σ	23	21	12	22	Superior vermian ICH	mRS 4, cerebellar ataxia	Failed at step 1	Rusch 8.5
ABI Acqu	ired bra	in iniur	V, CRS-r C	AB/ Acquired brain iniury. CRS-r Coma recovery scale. revised. F Ferr	cale. revised.	F Female, ICH Intrace	ale. <i>(CH</i> Intracerebral hemorchage. <i>(CU</i> Intensive care unit. <i>L</i> 05 Lenoth of stav. <i>M</i> Male. <i>m</i> 85 Modified Rankin Score. <i>MV</i> Mechanical ventilation. 54H	h of stav. M Male. m85 Modified Bankin Scor	e. MV Mechanical ventilat	ion. SAH

ABI Acquired brain injury, crs-r coma recovery scare, revised, i remare, rommover Subarachnoid hemorrhage, TBI Traumatic brain injury, TW Tracheostomy weaning

Table 1 Patient characteristics

6.4 mm, OD 10.8 mm). When performing tube capping, we used Shiley speaking valves exclusively. Prigent et al. [10] demonstrated that the work of breathing was higher when the Rusch speaking valve rather than when the Shiley valve was used.

The complete results are presented in Table 2.

No involvement of accessory respiratory muscles was recorded at step 0 or step 2.

From our findings, a speaking valve with a deflated cuff significantly enabled nasal respiratory airflow without the involvement of accessory respiratory muscles compared with a deflated cuff alone (Table 2, Fig. 1). However, we did not find a significant difference in the numbers of swallows between the two conditions (despite a tendency toward a higher number of swallows when a speaking valve was placed; see Table 2). Conversely, in an earlier study, Kim et al. [11] found qualitative improvement of swallowing function with the use of a speaking valve; however, the number of swallows was not included in the study results.

The difference in nasal airflow might be explained by the fact that, without a speaking valve, the shortest and easiest route for the airflow would likely be through the cannula. Chadda et al. [12] reported that the dead space above the cannula accounted for 30% of the workload. Therefore, if tube capping is not used to force airflow through the upper airway, the patient may breathe only through the cannula, even with a deflated cuff. This is in line with the findings of Prigent et al. [13], who found that expiratory flow after swallowing was present when a speaking valve was placed but was negligible without a valve. The presence of an inspiratory nasal airflow with a speaking valve is surprising because, theoretically, inspiratory airflow would be expected solely through the tube [14] (Fig. 1, step 2, a, b). The use of a speaking valve likely increases the respiratory workload to a level that allows inspiratory airflow around the cannula, and then through the upper airway, but not enough to engage the accessory respiratory muscles. Further studies are needed to confirm this hypothesis. Moreover, we found that this effect was maintained at 1 h (step 2 plus 1 h), proving that it is not simply a brief effect of speaking valve placement.

The major limitation of this study was the small sample size, which precluded us from drawing firm conclusions. However, to our knowledge, this is the first time that nasal airflow has been recorded during tracheostomy weaning of patients with ABI. The PG used to record nasal airflow could be replaced by a pneumotachograph [12]. Instrumental assessments and esophageal pressures would aid swallowing and respiratory workload assessments [15, 16]. Such examinations require that patients are moved out of their units, invasive devices are used,

Table 2 Nasal airflows at step 0, step 2, and step 2 + 1 h and the numbers of swallows at step 0 an	d step 2
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Variable	Step 0	Step 2	Step 2 + 1 h	Differences per patients	P value
Nasal airflow (step 0 vs. step 2) (cmH ₂ O)					
n	12	12			0.0049*
Mean (SD)	0.25 (0.24)	0.82 (0.71)		0.57 (0.64)	
Median (Q1–Q3)	0.19 (0.06–0.38)	0.51 (0.28–1.29)		0.32 (0.10–1.10)	
Min, max	0.01, 0.80	0.18, 2.23		- 0.21, 1.74	
Nasal airflow (step 0 vs. step $2 + 1$ h) (cmH ₂ O)					
<i>n</i> (m.d.)	12		11(1)		0.0293*
Mean (SD)	0.25 (0.24)		0.66 (0.61)	0.41 (0.59)	
Median (Q1 to Q3)	0.19 (0.06 to 0.38)		0.35 (0.19 to 1.14)	0.11 (0.00 to 0.86)	
Min, max	0.01, 0.80		0.01, 1.91	- 0.45, 1.58	
Nasal airflow (step 2 vs. step $2 + 1$ h) (cmH ₂ O)		12	11(1)		0.2324
<i>n</i> (m.d.)		12	11(1)		0.2324
Mean (SD)		0.82 (0.71)	0.66 (0.61)	— 0.16 (0.46)	
Median (Q1 to Q3)		0.51 (0.28 to 1.29)	0.35 (0.19 to 1.14)	-0.06 (-0.42 to 0.00)	
Min, max		0.18, 2.23	0.01, 1.91	0.01, 1.91	
Number of swallowing/5 min					
n	12	12			0.2715
Mean (SD)	2.5 (2.4)	3.7 (2.8)		1.17 (3.04)	
Median (Q1 to Q3)	2 (1 to 5)	4 (2 to 5)		1.50 (— 0.50 to 3.00)	
Min, max	0, 7	0, 10		- 4.00, 7.00	

The p values are for the Wilcoxon signed-rank test, * bold values are for p values < 0.05

Max, maximum, m.d., missing data, min, minimum, Q1, quartile 1, Q3, quartile 3, SD, standard deviation

and patients can cooperate; additionally, they cannot be performed simultaneously. Thus, such assessments are at least difficult and may be dangerous when tracheotomy weaning is initiated.

To conclude, the use of a speaking valve with a deflated cuff restores airflow through the upper airway more effectively than cuff deflation alone (Fig. 1, step 0, step 2). A speaking valve restores not only the expiratory nasal airflow but also, to a lesser degree, the inspiratory nasal airflow (Fig. 1). Hence, because restoring airflow in the upper airway is considered key during swallowing rehabilitation of tracheostomized patients, our findings seem to favor the use of a speaking valve rather than cuff deflation alone during tracheostomy weaning.

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Author Contributions

Conceptualization: TG, EC, JL, DC; Methodology: CG, OB; Formal analysis and investigation: TG, DC; Writing—original draft preparation: TG; Writing—review and editing: TG, EC, DC, CG, JL, OB, EC, PD, JE; Funding acquisition: TG, OB; Supervision: EC, PD, JE. The final manuscript has been approved by all authors.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical Approval/Informed Consent

This study was approved by the ethical committee of our institution (Notice Number: 17-12-08). This study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki. A written informed consent was obtained from all the patients included in this study or their associated legal representatives.

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