

Clinical implication of artificial glottic closure  
for air-stacking exercise in patients with glottis  
dysfunction

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dysfunction

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A man's heart deviseth his way: but the LORD directeth his steps.  
(Proverbs 16:9)

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『ABSTRACT』

**Clinical implication of artificial glottic closure for air-stacking exercise in patients with glottis dysfunction**

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Objective: Patients with neuromuscular disease can have severe inspiratory and expiratory muscle weakness that diminishes vital capacity and lung compliance. Atelectasis and inability to effectively cough out airway secretions are the main cause of respiratory failure and mortality. Therefore, air-stacking exercise which insufflates the lung to its maximal capacity is mandatory to maintain pulmonary compliance. However, neuromuscular patients with bulbar musculature weakness or indwelling tracheostomy cannot induce glottic opening and closure. For these patients, we developed a method which enables air stacking exercise by mimicking the glottis function.

Method: 40 patients with bulbar muscle weakness or indwelling tracheostomy were recruited. 26 were amyotrophic lateral sclerosis(ALS) patients, and 14 were tetraplegic patients due to cervical spinal cord injury(SCI). T-shaped device is mainly composed of the connection and the control part. One-way valve is installed to the connection part to provide extra volume of air via a manual resuscitator bag, which also prevents air leakage. The control part is designed to artificially modulate glottic opening and closure. In order to confirm the utility of external control device vital capacity(VC), maximum insufflation capacity(MIC), and maximum insufflation capacity with a device(MIC-device) were measured.

Results: For the 32 patients, MIC was not measurable initially. However, with help of the method which enables air stacking exercise, MIC-device was successfully measured for all patients. Mean MIC-device value was  $1701.9 \pm 660.5$ ml. For the remaining 8 patients, MIC was measurable even without the device, but mean MIC and MIC-device values were  $1073.8 \pm 242.4$ ml,  $1847.5 \pm 233.7$ ml respectively. MIC-device of the patients was significantly higher than MIC alone.

Conclusion: The new method enables air staking, which is mandatory for lung expansion. It also makes it possible to maintain or even improve pulmonary compliance,



which eventually prevents lethal pulmonary complications.

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Key Words: glottis dysfunction, air-stacking exercise, maximal insufflation capacity

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## **I. INTRODUCTION**

Many patients with neuromuscular disease(NMD) are characterized by progressive weakening of skeletal, respiratory, and or bulbar muscles.<sup>1</sup> NMD patients with respiratory muscle weakness shows decrement in vital capacity(VC), lung and chest wall compliance, and coughing capacity. These patients cannot expand their chest fully, which leads to stiffening of joints and tissue of the rib cage, then a reduction in chest wall compliance.<sup>2</sup> Reduction in lung and chest wall compliance may also be related to alterations in the elastic properties of lung tissues by chronically limited range of activity.<sup>3</sup> Normal breathing consists of varying tidal volumes with intermittent deep breaths or sighs.<sup>1,4</sup> Even in people with normal lung, periodic hyperinflation is required to prevent closure of lung units.<sup>1</sup> Not to speak of NMD patients whose tidal volume is often reduced, periodic deep insufflation through air-stacking exercise is an essential element.

Air stacking involves the use of manual resuscitator to deliver volumes of air that are consecutively held by glottic closure until no more air can be retained.<sup>5</sup> The maximum lung volume that can be held by air-stacking is the maximum insufflation capacity(MIC).<sup>6</sup> In 2000, Kang had demonstrated that lung volumes could be augmented significantly over VC by air

stacking to approach MIC for patients with NMD.<sup>1,7</sup> Whereas most important exception for this is that of amyotrophic lateral sclerosis(ALS) patients with dysfunctional bulbar musculature.<sup>1</sup>

Normal coughing process is an essential element for intra-tracheal mucus clearance.<sup>8</sup> Ineffective coughing out airway secretion is the main cause of respiratory failure in patients with NMD.<sup>1,9</sup> For neuromuscular and cervical SCI patients who have weakened respiratory muscles, effective coughing can be performed only with assistance.<sup>10,11</sup> Until now, the best-known assisted cough method is the manual assisted cough, which is performed by thrusting the patient's abdomen during maximal voluntary cough after maximal inhalation.<sup>10</sup> In addition to enough expiratory force, augmentation of lung air volume is essential to optimize peak cough flow (PCF) in pre-cough stage. One of the best known methods of lung inflation is air stacking.<sup>6</sup> However, patients with NMD have a difficulty in obtaining a sufficient PCF with an abdominal thrust alone because of their inability to inhale sufficient volumes by their own efforts due to weak respiratory muscles.<sup>12,13</sup> Therefore, it is effective to carry out a manual assisted cough by supplying additional air to the patient's lungs with a manual resuscitator bag after the patient's maximal inhalation.<sup>1,6</sup> However, patients presenting inappropriate glottis closure due to bulbar musculature dysfunction or indwelling tracheostomy under the glottis level can not hold the inhaled volume of air voluntarily inside of their lungs. Consequently, they can not induce an increment of intra-thoracic pressure by the contraction of their expiratory muscles.<sup>14</sup> Carrying out an air-stacking exercise is very difficult for patients with abnormal glottis function, although air-stacking exercise is crucial, because atelectasis or contracture of the thoracic cage leads to reduced lung compliances, making it difficult to assist coughing by air supplementation during inspiratory period.

In this study, we designed a method which provides external control of glottic opening and closure for patients with glottis dysfunction due to bulbar musculature weakness or indwelling tracheostomy tubes. By adopting this method, we attempted to investigate the effectiveness of

air-stacking exercise by replacing dysfunctional glottis.

## II. MATERIALS AND METHODS

### A. Artificial external glottis device

T-shaped device is mainly composed of the connection and the control part. The connection part is a t-shaped plastic pipe, and has three main pathways. The control part is designed to artificially modulate glottic opening and closure.

#### (1) The connection part

As shown in fig 1&2, the connection part is a T-shaped plastic pipe with three main pathways: the patient connection port, the insufflation port, and the exsufflation port. The patient connection port is a pathway that connects directly with the patient's airway through a tracheostomy tube or an oronasal mask (fig 1-A). The insufflation port is located in the middle of the cylindrical structure at a right angle, and it serves as a pathway of air-volume support with the manual insufflating bag for cough induction. To supply air-volume effectively, the previous inhaled air should not leak through to the prior air pathway. Therefore, a one-way valve is installed in the insufflation port (fig 1-A). The exsufflation port is an air pathway that is connected to the control part.

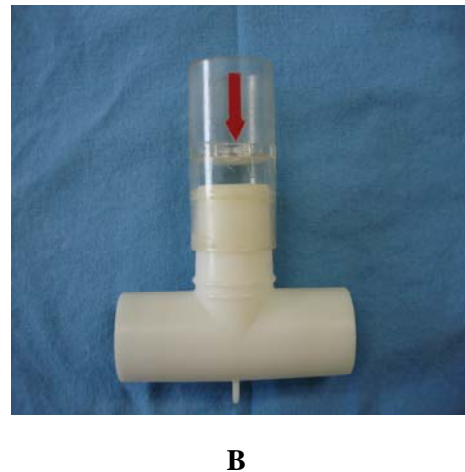
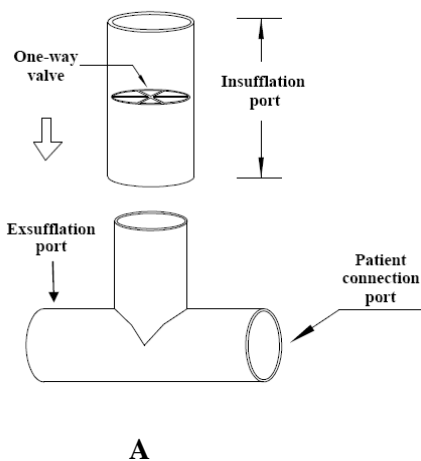


Fig.1 Detailed diagram of the connection part of device: when measuring MIC-device previously inhaled air does not leak out because of the one-way valve.

A) demounted view, B) assembled view for the connection part.

(2) The control part

The control part, which takes charge of the core function in this device, artificially modulates glottic opening and closure. As shown in fig 3&4, the function of glottic opening and closure is regulated by a pushing bar. The tip of the pushing bar protrudes from the outer wall of the control part, and it works as a push button. Before pushing the button, airflow is stopped in between the connection and the control part. When the button is pressed, concave portion of the pushing bar is exposed to the connecting tube, and exhaled air is passed through this space. A spring is inserted into the connecting axis of the pushing bar, and this axis is designed to pass through the center of the hole in the disc, which acts as an air pathway.(fig.3) In non-operating state, airflow to the connecting tube is completely interrupted by the pushing bar, which is fixed due to the recoil of the spring and support action of the disc hole. However, once the button is pressed, the pushing bar moves towards the connecting tube with exhalation, and it comes back to the interruption state when the button is released. Therefore, patients are allowed to exhale by pressing the push button of the device after increasing the intra-thoracic pressure through the air-stacking exercises.

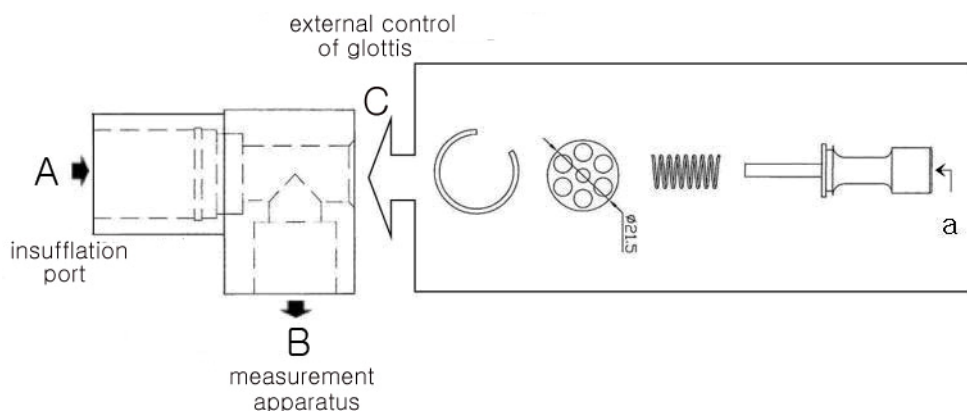
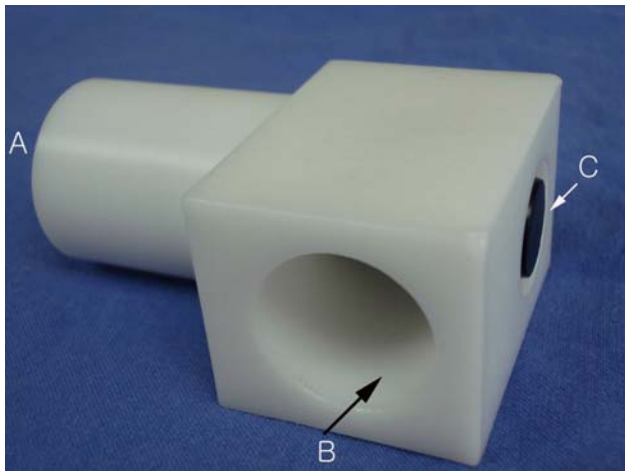


Fig 2. Detailed diagram of the control part of device

A) Demounted view of the control part of device: Control part is connected to the connection part: A, and measurement apparatus such as a spirometer B, the external glottic function is controlled by a externally exposed part of the pushing bar a), air flows from A to B like opening of a normal glottis



B) Photograph of the control part of device: A, connection part; B, measurement apparatus such as a spirometer; C, external control of the glottis

### *B. Clinical evaluation*

The institutional review board approved this study, and informed consent was obtained from all of the study candidates. In order to assess the clinical utility of artificial glottic method, 40 neuromuscular disease patients with bulbar muscle weakness or indwelling tracheostomy tubes were recruited. Exclusion criteria were the following: inability to cooperate attributable to severe cognitive impairment, medical instability, and primary lung and airway rather than chronic respiratory insufficiency. All lung volumes were measured by Micro spirometer (Micro Medical Ltd., Rochester, Kent, UK) and recorded as the greatest observed value in at least three attempts.

Outcome measurements were as follows:

- (1) Vital capacity (VC) was measured in a sitting position by using a Micro spirometer

(Micro Medical Ltd., Rochester, Kent, UK). Subjects were asked to take a deep breath, then exhale the maximally held volume of air into a Micro spirometer.

- (2) Maximum insufflation capacity (MIC) was measured in a sitting position using the same equipment. Patients were told to take and hold a deep breath then extra volume of air was delivered consecutively via an oro-nasal interface by using a manual resuscitator bag. The maximally stacked volume of air was measured by having the patient blow the entire volume through the Micro spirometer. The maximum value that was observed in at least three attempts was recorded as the MIC.
- (3) MIC with the device (MIC-device), which replaces the impaired glottis function, was measured by the same method as the MIC. Artificial glottic opening device (fig 5) was installed to prevent leakage of the supplied air. This process was repeated at least three times, and the greatest value was selected as the MIC-device value.



Fig. 3 A fully assembled apparatus for measuring MIC-device: A resuscitation bag is connected to the external control device





Fig. 4 Actual application of the apparatus for measuring MIC-device: NMD patient presenting glottis dysfunction due to bulbar muscle paralysis

### *C. Data analysis*

A Wilcoxon signed-rank test was used to determine the statistical significance between MIC and MIC-device. Data was analyzed using SPSS 12.0<sup>b</sup>, and a p-value  $<0.05$  was considered statistically significant.

### III. RESULTS

Forty NMD patients were evaluated to assess the clinical implication of artificial glottic closure for air stacking exercise (table 1). 26 were previously confirmed ALS patients, and the other 14 were tetraplegic patients due to cervical SCI sustaining complete motor injuries, as defined by American Spinal Injury Association criteria. All of the SCI patients and 12 of the ALS patients were indwelling tracheostomy tubes (table 1,2). Fourteen of the study candidates were female and 26 were male. The mean age of all candidates was  $48.1 \pm 13.3$  years old.

Table 1: Subject Characteristics and Pulmonary Evaluation Results

Case	Sex	Age (years)	Tracheostomy	Diagnosis	VC (ml)	MIC (ml)	MIC-device (ml)
1	M	39	Y	SCI(2C)	1150	Fail	1900
2	M	25	Y	SCI(3A)	230	Fail	2350
3	F	25	Y	SCI(2C)	430	Fail	1970
4	M	44	Y	SCI(4A)	350	Fail	1560
5	F	48	Y	SCI(2A)	800	Fail	1690
6	M	63	Y	SCI(3A)	450	Fail	1720
7	M	59	Y	SCI(4A)	1970	Fail	2700
8	M	37	Y	SCI(3B)	380	Fail	2100
9	M	40	Y	SCI(7B)	1300	Fail	2500
10	M	21	Y	SCI(2A)	Fail	Fail	800
11	M	20	Y	SCI(7A)	1080	1470	1840
12	M	42	Y	SCI(3A)	680	Fail	2360
13	F	41	Y	SCI(5A)	440	Fail	1620
14	F	60	Y	SCI(4A)	460	Fail	1100
15	M	40	N	ALS(B)	1350	Fail	1550
16	M	43	N	ALS(B)	1620	Fail	2050
17	F	51	Y	ALS	800	Fail	1200
18	F	50	Y	ALS	330	Fail	800
19	M	57	N	ALS(B)	850	Fail	1250
20	M	56	N	ALS(B)	1050	Fail	1910
21	F	54	N	ALS(B)	1110	Fail	1540

22	F	45	N	ALS(B)	920	1050	1650
23	F	55	N	ALS(B)	650	Fail	1700
24	M	49	N	ALS	2400	Fail	4000
25	F	70	N	ALS(B)	350	Fail	900
26	M	39	Y	ALS	730	1290	1830
27	M	55	Y	ALS	940	Fail	1700
28	M	55	Y	ALS	710	840	2050
29	M	33	Y	ALS	450	710	2290
30	F	54	N	ALS(B)	920	1040	1540
31	M	44	Y	ALS	750	Fail	1050
32	M	76	Y	ALS	820	Fail	1320
33	M	45	Y	ALS	Fail	Fail	1630
34	M	49	Y	ALS	Fail	Fail	1930
35	F	74	Y	ALS	620	Fail	2050
36	F	61	Y	ALS	680	Fail	890
37	M	37	N	ALS(B)	1140	1190	1840
38	F	66	N	ALS	690	1000	1740
39	M	44	N	ALS	1120	Fail	1780
40	M	58	N	ALS(B)	510	Fail	840

Abbreviations: VC, vital capacity; MIC, maximum insufflation capacity; MIC-device, maximum insufflation capacity with device; SCI(2C), spinal cord injury(neurologic level of injury, American spinal injury association impairment scale); ALS, amyotrophic lateral sclerosis; ALS(B), bulbar dominant amyotrophic lateral sclerosis; M, male; F, female; Y, yes; N, No

Table 2. Comparisons of parameters according to diagnosis

<b>Diagnosis</b>	<b>No.</b>	<b>Tracheostomy</b>	<b>Age (years)</b>	<b>VC (ml)</b>	<b>MIC (ml)</b>	<b>VIC –device (ml)</b>
<b>ALS</b>	<b>26</b>	<b>12</b>	<b>52.3±11.0</b>	<b>896.3±440.7</b>	<b>1017.1±196.6</b>	<b>1655±633.7</b>
<b>SCI</b>	<b>14</b>	<b>14</b>	<b>40.3±14.1</b>	<b>747.7±500.6</b>	<b>1470±0</b>	<b>1872.1±524.2</b>

NOTE. Mean values ± SD (ml)

Abbreviations: VC, vital capacity; MIC, maximum insufflation capacity; MIC-device,

maximum insufflation capacity with device; SD, standard deviation; ALS, amyotrophic lateral sclerosis; SCI, spinal cord injury

Of the 40 study patients, 32 patients had little remaining glottis function, and they could not hold air volume at all. Thus, their initial MIC values were not measurable. After applying external artificial glottis which bypasses the glottis function, all of the 32 patients were able to stack sufficient volume of air. As a consequence, the mean MIC-device value was measured as  $1701.9 \pm 660.5$  ml.

In accordance with underlying pulmonary function, the 32 patients were subdivided as group 1 and 2 (table 3). Group 1 included three patients who presented severe inspiratory and expiratory muscle weakness as well as bulbar musculature paralysis. Since their respiratory muscles were too weak to even take a deep breath and to exhale, VC and MIC could not be checked as numerical values. Group 2 included 29 patients for whom only MIC was not checkable. After applying external glottis method, MIC-device was successfully measured in both groups (table 3).

The other 8 patients had minimal residual glottis function to hold and stack a little volume of air. They were named as group 3 (table 3). Mean VC and MIC in this group were  $830 \pm 227.8$  ml and  $1073.8 \pm 242.4$  ml, respectively. MIC was significantly higher than VC. Although MIC was measurable initially without bypassing glottis function, mean MIC-device was  $1847.5 \pm 233.7$  ml, which was significantly greater than MIC ( $p=0.012$ ).

Table 3. Comparison of pulmonary function parameters under different conditions.

	<b>VC (ml)</b>	<b>MIC (ml)</b>	<b>MIC-device (ml)</b>
<b>Group 1 (n=3)</b>	<b>NT</b>	<b>NT</b>	<b>1453.3±585.3</b>
<b>Group 2 (n=29)</b>	<b>847.9±510.4</b>	<b>NT</b>	<b>1727.6±671.7</b>
<b>Group 3 (n=8)</b>	<b>830±227.8</b>	<b>1073.8±242.4</b>	<b>1847.5±233.7*</b>

NOTE. Mean values ± SD (ml)

Abbreviations: VC, vital capacity; MIC, maximum insufflation capacity; MIC-device, maximum insufflation capacity with device; SD, standard deviation; NT, not testable

\*, p<0.05, comparison between MIC and MIC-device

#### IV. DISCUSSION

Coughing is a protective mechanism of human body which effectively expels airway secretions to prevent pulmonary complications.<sup>8</sup> In order to cough effectively, three phases of coughing should work in conjunction, which are inspiratory, compressive, and expulsive phase. Any problems in each phase can bring about an inadequate cough flow for removing the intratracheal secretions.<sup>15</sup> In the case of inefficient coughing, assistant techniques can be used to augment cough ability. Bach had compared several assist coughing methods, and demonstrated that manually assisted coughing and mechanical insufflation-exsufflation attained more pre-cough inspiration volumes and greater cough flows.<sup>10</sup> However, these methods cannot induce an effective cough in patients with respiratory muscle weakness or paralysis combined with bulbar muscle weakness and/or tracheostomy, because additionally supplemented air for assist coughing leaks out from the lungs in these patients.

If regular deep insufflation is not provided in NMD patients, they will first develop microatelectasis due to reduced VC, and then progress to a chronic hypo-inflation state that results in permanent pulmonary restriction.<sup>16,17</sup> In other words, decreased pulmonary compliance initially results in microatelectasis, and ultimately leads to the stiffening of lung and chest wall<sup>16-19</sup> The expansion impairment of lung parenchyma results in a limitation of sufficient air inhalation during pre-cough stage. Just like range of motion (ROM) exercise of all four extremities to avoid joint contractures, air stacking into the lung should be performed to preserve lung compliance in NMD patients.<sup>1</sup> However, NMD patients with bulbar muscle paralysis and/or tracheostomized patients can not benefit from proper air stacking exercises, because they can not prevent leakage of inhaled air from the lung.<sup>8</sup>

Therefore, this study was aimed to evaluate the utility of artificial glottis closure for air stacking exercise in patients with glottis dysfunction, and to see how this method influences on pulmonary function parameters in actual values. The method described in this study is designed

to provide external control of the air pathway by pressing a pushing bar, which operates like an artificial glottis. Even in cases with difficulty in performing air stacking exercise due to glottis dysfunction, external closure of the control part of our method enabled the patients to stack sufficient amount of air to induce the increment of intra-thoracic pressure high enough for an effective cough. When the control part is opened exactly in accordance with expulsion, measurements of MIC can be possible without air leakage. In this study, all patients whose initial MIC were unobtainable or who showed little difference between the MIC and VC without utilizing the method were able to come up with measurable MIC-device values with external artificial glottic control. Markedly-increased MIC-device compared with MIC was evident, and the difference was statistically significant.

In the process of connecting our device with the measuring instruments, the numerical value can be underestimated, because the exhaled air pathway of the connection system is a right-angled structure and not a straight line. Consequently, the fully assembled apparatus for measurement has a relatively long expiratory flow pathway. Speed of the flow can also be a problem. Thus, measured MIC-device values may actually be greater than those reported in this study.

## V. CONCLUSION

Air-stacking exercise, which enables deep insufflation, is considered as a cornerstone to maintain pulmonary compliance and thoracic wall ROM. However, patients with impaired glottis function cannot hold the stacked air into the lungs which consequently results in microatelectasis, decreased pulmonary compliance, and stiffening of lung and thoracic wall.

Our new method enables air stacking exercise by bypassing abnormal glottis function. This method aids in maintaining pulmonary compliance as well as assists coughing by providing external glottis closure in NMD patients with bulbar musculature weakness or tracheostomized patients who can not cough effectively with the help of existing assist coughing methods. Ultimately, this method can be used to prevent lethal pulmonary complications in NMD patients presenting abnormal glottis function.



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『ABSTRACT』

성문기능 장애 환자의 공기누적운동에서 인위적 성문폐쇄의 임상적 의미

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신경근육질환 환자들은 대부분 진행성의 호흡근의 위약을 동반하게 되며, 이로 인하여 폐와 흉곽의 유순도 및 폐활량이 감소되고 폐 내에서 무기폐 현상이 확산되게 된다. 기침능력의 약화에 따른 기도 분비물의 배출장애는 각종 호흡기계 합병증을 유발시키고 이는 환자들의 주요한 사망원인이 되어왔다. 따라서 폐를 최대 용적까지 팽창시키는 공기누적 운동은 폐 유순도 유지를 위하여 필수적이거나 연수근 위약을 보이거나 기관절개를 시행한 환자들은 성문의 개폐조절에 어려움을 겪게 된다. 본 연구에서는 외부에서 성문개폐기능을 대신해 주어 공기누적 운동을 가능하게 하는 방법을 이용하여 공기누적 운동이 이러한 성문기능 부전을 보이는 환자에게서 미칠 수 있는 임상적 의의에 대해 알아보하고자 하였다.

연수근 부전을 보이거나 기관절개 상태로 인해 공기누적 운동의 시행에 어려움이 있는 40명의 신경근육질환자들이 본 연구의 대상이 되었다. 26명은 연수근 위약이 있거나 기관절개 상태인 근위축성 측삭 경화증 환자였고 14명은 경수손상으로 인한 사지마비환자로 이들 모두는 기관절개 상태였다. T자 형태의 기구는 조절부와 연결부로 구성되어 기도 외부에서 공기흐름을 조절하여 성문개폐를 대신할 수 있게 하였다. 연결부에는 원웨이 밸브(one-way valve)가 부착되어 유입된 공기가 빠져나갈 수 없게 고안되었다. 조절부는 성문의 개폐기능을 외부에서 인위적으로 조절할 수 있게 하였다. 이러한 성문개폐 대체방법의 임상적 유용성을 평가하기 위하여 폐활량(vital capacity), 최대주입용량(maximum insufflation capacity) 및 인위적 성문개폐방법을 이용한 최대주입용량(MIC-device)을 측정하였다.

32명의 환자는 성문기능 부전으로 인해 MIC의 측정이 불가능하였다. 이들 모두는 인위적인 성문폐쇄 방법의 적용 이후 공기누적이 가능하게 되었고, 그 결과 평균 MIC-device값은  $1701.9 \pm 660.5$ ml로 측정되었다. 나머지 8명은 인위적 성문폐쇄 방법을 적용하지 않고도 MIC의 측정이 가능하였으나 MIC와 MIC-device의 평균값은 각각  $1073.8 \pm 242.4$ ml,  $1847.5 \pm 233.7$ ml로 MIC-device가 MIC에 비해 의미 있게 높게 측정되었다.

본 연구에서 적용된 인위적 성문폐쇄 방법은 폐 팽창에 필수적인 공기누적운동을

가능하게 하였다. 이를 통해 폐 유순도를 유지, 향상시킴으로써 궁극적으로 치명적인 호흡기계 합병증을 예방하는데 도움을 줄 수 있을 것으로 생각된다.

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핵심되는 말: 성문기능 부전, 공기누적 운동, 최대주입용량