Research Article ISSN 2639-9458

Microbiology & Infectious Diseases

Expiratory Flow Accelerator (EFA®) For Dysphagic Non-Coooperative Patients: A Pilot Study for Preventing Aspiration Pneumonia

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Received: 11 May 2023; **Accepted:** 13 Jun 2023; **Published:** 17 Jun 2023

Citation: MANDALÀ G, SANGUEDOLCE G, Gabriella SCACCIANOCE, et al. Expiratory Flow Accelerator (EFA®) For Dysphagic Non-Coooperative Patients: A Pilot Study for Preventing Aspiration Pneumonia. Microbiol Infect Dis. 2023; 7(2): 1-8.

ABSTRACT

Background: *"Ab ingestis" pneumonia is the second most common cause of nosocomial infections in inpatients and the most common cause of death in patients with dysphagia. Rates increase dramatically in patients with neurological diseases or an acquired brain injury. Early interdisciplinary rehabilitation protocols could reduce penetration-aspiration episodes.*

Aim: *This pilot study is aimed to investigate the effects of an expiratory flow accelerator (EFA®) device - usually aimed to manage airway secretions - in addition to usual care to prevent the penetration-aspiration (PA) risk in bedridden dysphagic low-alert patients, with ineffective cough, compared to a "usual care" control group. Patients from an intensive respiratory care unit were assessed by a multidisciplinary team and evaluated with FEES: 20 subjects were recruited in the EFA-group and 20 in the control group.*

Design: *Controlled study.*

Setting: *inpatients of PRM unit*

Population: *Neurological with recent aspiration pneumonia dysphagic patients vigilant an cooperative (control group) or non cooperative with disorders of consciousness and ineffective cough (study group).*

Methods: *We analyzed the use of expiratory flow accelerator with a protocol to prevent relapses of PA in study group and compared with traditional treatments in cooperative patients.*

Results: *After 21-weeks, aspiration pneumonia occurred in two patients of the study group and in three patients of the control group. All patients showed a reduction of daily need for suctioning ($p<0.0001$), without differences between groups ($p=0.53$). Improvements in the penetration-aspiration scale(PAS) and in the peak expiratory flow (PEF) was significant in both groups with a prevalence in the study group ($p = 0.0042$ and $p < 0.0001$, respectively).Non-cooperative patients, with four or more PA risk factors, treated with EFA®had outcomes similar to lower-risk patients treated with usual prophylactic care alone.*

Conclusion: *This preliminary research showed the feasibility and reliability of the EFA® to prevent PA episodes in high-risk dysphagic patients and provides the framework to design a trial.*

Clinical rehabilitation impact: *the use of efa technology could be assessed and used in patients with severe acquired brain injury and ineffective cough.*

Keywords
Dysphagia, Aspiration pneumonia, Acquired brain injury, Expiratory flow accelerator.

Introduction

Aspiration pneumonia (or "*ab ingestis*") is responsible for 13% to 48% of all lung infections in community health residencies and accounts for 5 to 15% of cases of community-acquired pneumonia [1]. It is the second most common cause of lung infections and the main cause of death for dysphagic patients. Rates increase dramatically in patients with neurological diseases [2,3].

Aspiration pneumonia is often caused by bacteria that normally reside in the oral and nasal pharynx. It can be referred to an infection caused by less virulent bacteria after a large volume aspiration event. But it is well-known that many community-acquired and hospital-acquired pneumonias result from small-volume aspiration of more virulent pathogens from the oral cavity or nasopharynx, such as *Streptococcus pneumoniae, Haemophilus influenza, Staphylococcus aureus,* and gram-negative bacteria [1].

Recurrent infections and pneumoniae due to aspirations can lead to chronic respiratory disorders, up to chronic respiratory failure. Episodes of penetration/aspiration of unwanted liquid and solid particles (including food, saliva or nasal secretions) inside the airways are closely related to swallowing disfunctions in the oral phase, time dilation in the pharyngeal phase, incomplete larynx elevation, incomplete clearance of glosso-epiglottic valleculae and pyriform sinuses from food particles. While inhalation of the gastric content can be directly toxic for the airways, other substances like food, rhino- and oropharyngeal secretions stimulate an inflammatory response and can be harmful if inhaled in large quantities. Depending on the acidity and bacterial load (mostly anaerobic bacteria) a chemical pneumonia can develop rapidly [4].

Normal cough reflex can efficiently protect the airways from this occurrence. However, several conditions can cause both swallowing and cough failure: from acute neurological disorders to neuromuscular degenerative diseases, and also mechanical blockage (such as from cancer or a history of intubation) and salivary alterations. Neurodegenerative diseases, such as Parkinson's disease, shows a reduced larynx sensitivity, impaired cough and incoordination between breath and swallowing are the major cause of silent aspirations. When these episodes occur, patients try to swallow repeatedly instead of coughing [5]. Risk factors includes also: gastroesophageal reflux disease, presence of endotracheal and/or nasogastric tubes, and all conditions that alter the state of consciousness [1].

Despite aspiration pneumonia remains the main cause of morbidity and mortality, dysphagia is often underestimated and screening tests are not routinely performed, even among population exposed to high risk. Instrumental investigations, such as fiberoptic endoscopic evaluation of swallowing (FEES) and pulmonary function tests (PFT), allow to intercept swallowing alterations in the early stages even in asymptomatic patients, before advanced clinical complications affect the quality of life and conservative treatment options become limited. In these patients, a reduction in forced vital capacity (FVC), forced expiratory volume in first second (FEV1) and peak expiratory flow (PEF) might suggest to explore an asymptomatic dysphagia [6,7].

Management of dysphagic patients is complex, above all after "ab ingestis" pneumonia, and requires an interdisciplinary approach, both for diagnosis and treatment. Early prevention strategies and rehabilitation can reduce risk of complications and its related social and economic impact [8]. The usual care includes the delivery of targeted speech and language therapy to improve swallowing and respiratory physiotherapy to improve cough effectiveness and manage bronchial and upper airways secretions, the change in consistency of food and liquids to make them safer to swallow and an adequate prophylaxis to avoid a pneumonia relapse (i.e., an accurate oral hygiene and optimal secretion management). Alternative forms of feeding (tube feeding through the nose or stomach) are used in severe condition [9]. However, in some cases it is difficult to apply these methods that usually require an active collaboration by the patient.

The aim of this pilot study is to verify the feasibility of a multidisciplinary protocol including, the application of an expiratory flow accelerator (EFA®) device, added to usual prophylaxis, to manage secretions and keep clear the upper airways, in bedridden dysphagic non-cooperative patients with ineffective cough. Since no other clinical trials exists for EFA® technology in patients with severe acquired brain injury and high-risk for recurrent pneumonia, results will be used as preliminary analysis to estimate and correctly outline the sample size and the statistical power for further randomized trials Figure1.

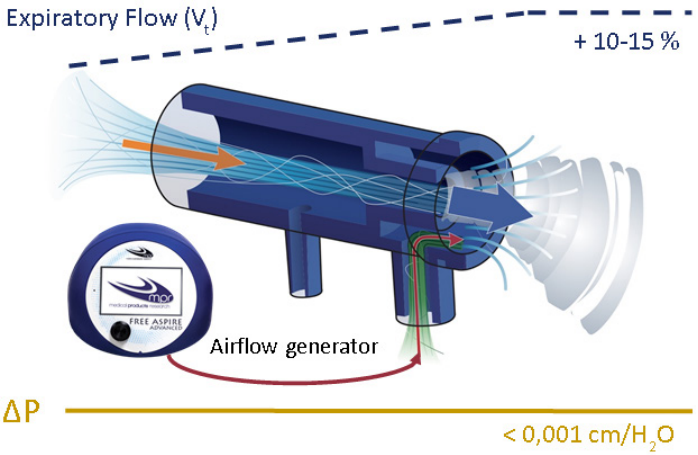

Figure 1: Schematic representation of the Expiratory flow accelerator (EFA® - Medical Product Research – Italy) used in this study. EFA is a patented technology aimed to gently mobilize bronchial mucus up to larynx or the tracheostomy tube, while the patient breathing at tidal volume. During spontaneous exhalation, the expiratory flows are accelerated by a Venturi effect. The system is studied to avoid any suctioning (negative pressure) effects in the airways.

Materials and Methods

All consecutive patient with an acquired brain injury (head-brain trauma, severe brain anoxia following a cardiorespiratory arrest, ischemic or hemorrhagic cerebrovascular accident, intracranial expansive oncological formations both in pre- and post-operative) admitted to our respiratory intensive care unit (RICU), "Buccheri La Ferla- Fatebenefratelli"Hospital in Palermo, from November 2017 to October 2019, and already weaned from mechanical ventilation support, were considered for enrollment.

All the subjects (or their legal guardian) and their relatives or caregivers, have been informed in advance about the characteristics of the protocol and the purposes of the study and signed an informed consent.

We included subjects aged between 18 and 85 years, hospitalized for an acute respiratory failure from pneumonia localized in the right lower lobe (confirmed by chest CT scan and hematochemical tests) or presenting at least 2 of the clinical predictors of prandial aspiration (abnormal volitional cough, abnormal gag reflex, dysphonia, dysarthria, cough after swallow, and voice change after swallow) or already diagnosed as dysphagic.

Exclusion criteria were: unstable clinical conditions or with poor prognosis at admission; oncology issues or waiting for a neurosurgical intervention; need for mechanical ventilation support during the day and/or the night; need for a nasogastric tube; lacking of caregiver support after discharge; refusal of the informed consent (by the patient or legal guardian). Presence of a tracheostomy tube or a percutaneous endoscopic gastrostomy (PEG) tube were not considered as exclusion criteria. Global physical and functional evaluation were performed at admission (T0) by clinicians and healthcare professional, while specific screening for swallow competence were performed within the 4th day from admission. Patients recovered from coma should still have a minimal state of consciousness at the Coma Recovery Scale, or at least the ability to maintain a state of prolonged and persistent vigilance.

Measures

The main outcome was the global number of aspiration pneumonia during the 21 weeks of observation. Secondary outcomes were:

- number of suctioning exceeding the daily oral (or tracheostomy tube) hygiene (once a day),
- penetration-aspiration scale (PAS) score (from 1 "Material does not enter airway" to 8 "Material enters the airway, passes below the vocal folds, and no effort is made to eject") [10]
- dysphagia outcome and severity scale(DOSS) score [11].
- pooling score [12]

With FEES we evaluate the presence of stagnations, penetrations and/or aspirations (PA) in the pre, intra and post swallowing phase [13]. A speech therapist tested both speech and non-speech tasks (such as oral praxis [14], articulatory diadochokinesis [15], and sustained vowel phonation [16]) Swallowing functions were tested through clinical screening tests: DOSS score [11], pooling score [12], penetration aspiration scale [10], bedside swallow assessment [17]. The cough reflex was tested stimulating the larynx sensitivity during FEES performing a "glottic-free cough PEF", while measured by a portable peak flow meter when patient could voluntary cough: a peak cough expiratory flow (PCEF) > 270 l/min, was considered normal and cough valid to protect airways from inhalation [18,19].

During the treatment period we record the lower right lobe pneumonia relapses and the number of daily suctioning. All measures and evaluations were repeated at 7, 14 and in the follow-up at 21 weeks from the first evaluation. Data from first (pre) and at 21 weeks evaluation (post) were considered for this study.

Treatment

Among patients who met eligibility criteria, non-cooperative and weak cough reflex patients, who had to be assisted and monitored to prevent PA episodes, were assigned to the study group. Collaborative ones with effective cough (PEF ≥ 270 l/min) showing less risk factors for PA, and a satisfactory collaboration sufficient to protect airways, acted as control group following the standard care protocol.

During the hospital stay only, the individualized interdisciplinary rehabilitation program included speech therapy and respiratory physiotherapy aimed to improve swallowing coordination and secretion removal. Program included also routine nursing, physiotherapy for functional motor disorders, orthoptist, nutritionist and neuropsychologist interventions, as needed.

The *control group* follow the usual care protocol for dysphagic patients proved to be effective since 2017 in our Department for cooperative patients. It involves a prophylaxis protocol to avoid care-related infections, which includes nasal and rectal bacteriological swabs, cleansing of the oral cavity from food residues after meal and daily oral hygiene with chlorhexidine-based (0,2 %) mouthwashes, weekly complete shower and shampoo with chlorhexidine-based soap.

In this group, speech therapy included forced apnea and production of glottic sounds to favor the vocal cords adduction; dry swallowing with the use of supraglottic swallow; thermal stimulation with ice for sensitivity of the palatine pillars; passive or active oral-motor stimulation to strengthen muscle tone and reduce pre-swallow; oral stimulation and voluntary activation of the oral phase (chewing, displacement of the bolus in the oral cavity). In addition, we treated dysphonia including controlled breathing, non-audible expiratory breath exercises, forced apnea, production of glottic sounds and vocalizations, controlled reading exercises.

Standard respiratory physiotherapy involves postural care to reach at least the sitting position or verticalization where reachable; passive/active mobilization and reconditioning with incremental aerobic exercises for legs and arms, for 20 minutes twice a day. All patients performed two 15 -20 minutes daily sessions of

positive expiratory pressure (PEP) therapy, via an oronasal mask or directly connected to the tracheostomy tube, and active forced expiration or cough, if needed. Flow-dependent resistance was set to maintain 10 to 20 cmH2O during the expiratory phase, with the aim of lung expansion and mucus clearance augmentation.

The study group non-cooperative patients, in addition to the prophylaxis protocol and logopedic stimulations (during the hospital stay), were treated with EFA® (Free Aspire- Medical Product Research, Italy), a device aimed to clear bronchial secretions in a non-invasive way, and without the need of active collaboration from the patient. We chose to add EFA® as suggested in previous studies that showed a reduction in respiratory exacerbation and in the need for suctioning in non-cooperative patients [20,21]. EFA® technology (Figure 1) allow to gently accelerate (by about 10%) the expiratory flow when breathing at tidal volume into a special "venturi" valve [22].

The device valve was connected to the patient via an oronasal mask or directly to the tracheostomy tube. Treatment was delivered in sitting position or, if bedridden, raising the head-of-bed by 30 degrees, for 15 to 20 minutes, three times during the daytime. Normally, secretion that slowly reach the epiglottis and pharynx pass into the esophagus [23]. In our patient, only when a big amount of secretion reached the mouth, they were suctioned. If a cuffed tracheostomy tube were present, secretion reaching the cannula were easily suctioned.

Before discharge, caregivers were trained to the use of the EFA®device (only study group) and prophylaxis. The actual adherence to the prescribed protocol at home were verified by the home health-assistance, during the planned outpatient follow-ups and during a weekly telephone call.

Table 1: Population characteristics.

	Studygroup	Control group	p
Subjects n° (M/F)	20 (12 F, 8 M)	20 (10 F, 10 M)	-
Age (mean, SD)	62,4 (±12,3)	66,8 (±14,7)	0,742
Risk factors for dysphagia (n)	4,27 (±1,32)	3,43 (±1,89)	0,127
Tracheostomized (n)	15	13	-
Percutaneousendoscopicgastros-tomy (n)	13 PEG tube (7 Nasogastric Tube)	5 PEG tube (15 Nasogastric Tube)	-

Statistical Analysis

As this is a pilot study with no previous comparable trials, no statistical power could be calculated.
Statistical analysis was performed with R Core Team (2018), a language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria).

The data are expressed as mean and standard deviation or as percentage for event incidence. Paired t-test or paired Wilcoxon test (non-parametric data) were applied for within-group differences. Unpaired t- and Wilcoxon test were applied for between-group differences. Differences between-groups were also verified after adjusting for baseline differences using an analysis of covariance. Differences between events incidence and proportions was detected by Chi-square test. Data distribution was evaluated with the Shapiro–Wilk test. P values <0.05 were considered statistically significant. We used the TREND checklist as a guide where applicable.

Results

We screened for dysphagia and "ab ingestis" pneumonia 72 consecutive patients admitted to our RICU from November 2017 to October 2019.42 patients were eligible for this pilot study and 40 of them (22 F; 18 F) completed the study protocol until the follow-up at 21 weeks. In the EFA group one died for cardiac complications, while other patient dropped-out at the first follow-up for personal reasons. Summary of baseline population characteristics are reported in Table 1. The table 2 shows the results of the main and secondary outcomes.

At the end of the study, all patients reduced considerably the needs for suctioning during the day (-88.89% in the group EFA® and -88.18% in the control group, $p < 0.0001$) and DOSS score ($p < 0.0001$), with no difference between groups. During the 21 weeks of observation, aspiration pneumonia occurred in two patients the of study group and in three patients in the control group. Improvements in the PAS was significative in both groups ($p < 0.0001$) with a prevalence in the study group ($p = 0.0042$). PEF had a significant post-treatment improvement in both groups ($p<0.0001$), without significant differences at the end of the study. Nonetheless, EFA® group, starting from a lower value, had a more clinically significant gain (+61,73%)compared to the control group (+14,38%). At baseline 10 patients in the EFA group showed a PEF<180 L/min, and only 5 of these were just below 270 l/min at the end of the study. During the observation period, only two subjects in the study group suffered a respiratory exacerbation and three in the control group.

Discussion

Results from this first observational study showed that the EFA®, combined with the usual prophylaxis protocol, reduced the occurrence of PA episodes and pneumonia in non-cooperative patients with weak or ineffective cough reflex. Moreover, at the end of the observation period, the study group showed outcomes comparable to the group of vigilant, collaborating and effective cough patient, which did not have the same serious PA risk factors.

Both groups showed a statistically significant difference in all outcomes between pre- and post-treatment, while no differences were found in the PA pneumonia relapses, in the number of suctioning exceeding the daily oral (or tracheostomy tube) hygiene and in the DOSS score Figure 2.

Hayashi et al. in 2014 [24] found that patients with AP had more severe disease, required longer hospital stays, and had a frequent recurrence rate of pneumonia and higher mortality. While AP was not a significant indicator for prognosis, it was indicated as the strongest risk factor for recurrence of pneumonia. In our study

Table 2: summary of the main results.

	EFA® group (n = 20)			Control group (n = 20)			EFA® group vs Control group	
	Pre	Post	p-value	Pre	Post	p-value	p-value pre	p-value post
Daily suctioning (Out of post EFA® hygiene)	4.95 (1.70) °	0.55 (0.75)	< 0.0001****	5.50 (1.73)	0.65 (0.75)	< 0.0001****	0.3066	0.5380
DOSS	1.70 (0.73) °	4.35 (0.75) °	< 0.0001****	1.65 (0.81) °	4.35 (0.75) °	< 0.0001****	0.7448	0.8750
PAS	7. 15 (0.81) °	2.15 (0.67) °	< 0.0001****	6.50 (1.19) °	2.50 (1.10) °	< 0.0001****	0.0801	0.0042 **
Aspiration Pneumonia	20 (100 %) ^	2 (10%) ^	< 0.0001****	20 (100%) ^	3 (15%) ^	< 0.0001****	> 0.9999	0.3924
PEF [l/min]	179.00 (31.44) °	289.50 (35.31) °	< 0.0001****	295.50 (26.65) °	338.00 (24.41) °	< 0.0001****	< 0.0001****	< 0.0001****

°Data shown as Mean (SD)
^ Data shown as number of patients with recurrent pneumonia (percentage)
** Significantly different p<0.01 (95% confidence interval)
**** Significantly different p<0.0001 (95% confidence interval)

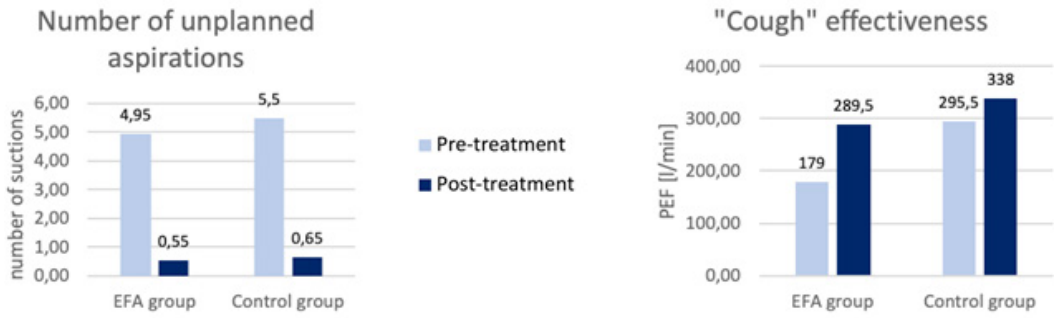

Figure 2: Both groups showed improvements in the outcome measures of dysphagia. The EFA® group reached a better score compared to the control group (p=0.004) in the PAS. Both groups showed a similar and meaningful clinical change (-55%) in the functional severity of dysphagia. PAS: Penetration Aspiration Scale; DOSS: Dysphagia Outcome and Severity Scale.

group, despite the worse initial condition and a higher PAS score (7. 15 ± 0.81) patients had a more significant improvement (5 ±0.79 points) compared to control group (4 ±0.86 points) at the end, suggesting a good management of mucus and saliva in the upper airways during the observation period.

Taylor et al. in 2013 [25] in an observational study of 1348 hospitalized patients, found that those at risk of aspiration pneumonia had a poorer short-term outcome (30-day mortality 17.2% vs 7.7%, P < .0001).They were at greater risk of poor long-term outcomes with increased 1-year mortality (hazard ratio [HR], 1.73; 95% CI, 1.15-2.58), increased risk of rehospitalization (HR, 1.52; 95% CI, 1.21-1.91), and a strong association with recurrent admissions with pneumonia (HR, 3.13; 95% CI, 2.05-4.78).

In 2017 Noguchi et al. [26] categorized a cohort of 322 patients by the number of PA risk factors (0-1, 2, 3, and 4 or more). 93 (28.9%) had 0-1 risk factors, 112 (34.8%) had 2, 88 (27.3%) had 3, and 29 (9.0%) had 4 or more risk factors. The percentages of patients with recurrence of pneumonia were 13.0%, 33.0%, 43.2%, and 54.2% respectively. The percentages of patients with 30-day mortality were 2.2%, 5.4%, 11.4%, and 24.1%, and those of patients with 6-month mortality were 6.6%, 24.5%, 30.7%, and 50.0%, respectively.

Yoon et al. in 2019 [27] in a total of 441 subjects found that the 1-, 3-, and 5-year mortality rates were 49.0%, 67.1%, and 76.9%, respectively. Multivariate analysis identified 5 risk factors for 1-year mortality of male sex [hazard ratio (HR) 1.533, P = .003], low body mass index (HR 0.934, P = .002), hypoalbuminemia, anemia (0.973, P = .032), and mechanical ventilation (HR 2.052, P < .001), which were also independent prognostic factors for 5-year mortality. During the follow-up period, 133 (24.2%) patients experienced recurrent aspiration pneumonia.

All patients included in our trial group had more than 4 PA risk factors. Nevertheless, all of them completed the observational period and, after treatment, only 2 (10%) of the study group patients had a pneumonia episode, while 3 (15%) in the control group. Also, in the study group the peak expiratory flow, measured during the FEES, pass the threshold of 270 l/min in 15 of 20 patients (mean value 289, 50 ± 35.31 l/min) and the other were

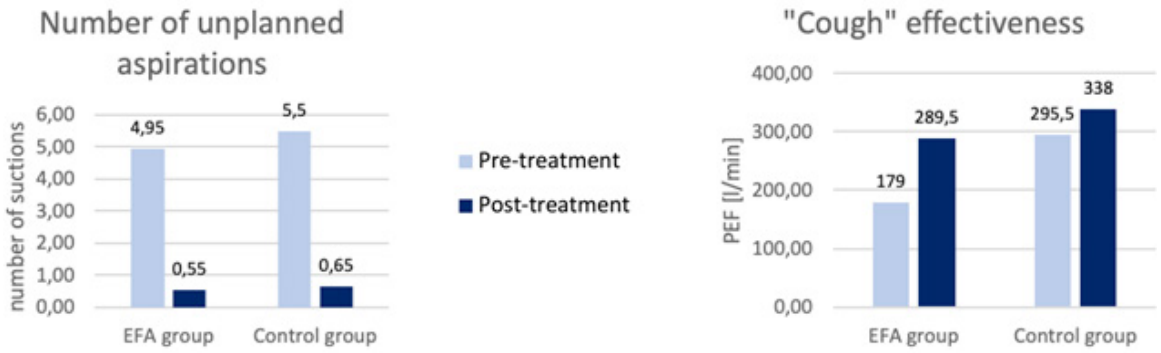

Figure 3: Both groups showed a similar reduction ($p<0.0001$) in the number of unplanned aspirations (-88.89% in the group EFA® and -88.18% in the control group), without a statistically significant difference between the two groups following treatment. PEF had a significant post-treatment improvement in both groups ($p<0.0001$), while the magnitude of gain was in favor of the EFA® group that started from a lower value (+61,73% vs +14,38%). PEF: peak of expiratory flow measured stimulating the larynx sensitivity during FEES performing a "glottic-free cough PEF".

just below, suggesting a better possibility to protect airways, at the last follow-up Figure 3.

There is a relationship between cough peak flow and dysphagia: the increase in cough peak greatly reduces the number of aspirations in dysphagics people both after surgery and in neurological patients [28,29]. Preliminary evidence also suggests that expiratory muscle strength training with progressive overload may improve airway protection in adults with dysphagia due to Parkinson's disease or stroke [30]. However, this strategy requires an active collaboration and a big effort by the patients. Conversely, EFA® is applicable to all spontaneously breathing patients without any collaboration required. Similar results were recorded in various case reports from the same rehabilitation unit, using the same technology in dysphagic patients after gastrointestinal surgery [Sanguedolce G, La Mantia V, Scaccianoce G, Sorrentino A, Mandalà G, "Effectiveness of the EFA® technology in the prevention of respiratory problems associated with deficit of the swallowing act, clinical case in patient with adenocarcinoma of the gastro-esophagus joint trated surgically affected by severe dysphagia". Acts of the national congress SIMFER 2017]; and [Sorrentino A, Scaccianoce G, Mirabella F, La Mantia V, Mandalà G. "Evaluation and Management of Patient Logopedic Dysphagia with Oncology and Esophagus-Colon-Plastic Cervicotoracic and Paralysis of the Recurrent Nerve: a case report". Acts of the National Congress F.L.I. Palermo 2018].

We believe that the supervision of family members has been crucial to ensure therapeutic adherence and to guide daily treatment at home. Patients in the study group which concluded the protocol without episodes of exacerbation, showed improvements in all outcomes and caregivers declared they attended all the compensation strategies prescribed with a constant use of the EFA® device. Caregivers of the 2 patients who had a pneumonia relapse declared that, after an initial improvement, worsening of symptoms appeared after a period of less adherence to the prescribed preventive strategies and EFA® therapy.

Speech therapists and respiratory physiotherapists were essential in the care and rehabilitation process, but mostly they had a key role in the choice of the individualized strategies to manage dysphagia, to educate and to support patients, their family and loved caregivers, to become aware of this problem, sometimes not identified, often underestimated or denied.

The training provided to caregivers during hospitalization allowed to choose the most appropriate interface for each patient. The outpatient visits and the planned telephone follow-up for patients discharged to their homes under integrated home care, allowed to monitor the actual adherence to the therapy.

This study had limits. Patient assignment to groups were not randomized and the risk of PA was different at the baseline assessment between groups. Nevertheless, considering the above-mentioned evidences about the incidence of respiratory complications and data from our experience, for ethical reasons we consider to treat all the patient at high risk of PA with the new technology.

Other considerations can be made about technical and organizational issues. The implementation of this trial underlined positive and critical aspects in the organization of inter-professional management of dysphagic patients. It has strengthened issues considered fundamental by the literature, translating them in our clinical practice. The early screening, included in the first visit by the physiatrist, made possible to identify those patients at risk of bronchial and pulmonary infections whose symptoms, although present, never have been routinely investigated in depth before. The execution of instrumental investigation such as the FEES, allowed to diagnose the extent of the swallowing deficit and to identify the severity of the dysphagia, better targeting the multidisciplinary intervention. Although of the study design was sufficient for the intended purpose, it need to be improved in order to optimize the multidisciplinary pathway and enhance the evidence with a wider randomized trial.

Conclusions

The use of EFA® technology, added to an early multidisciplinary management of dysphagia, allowed non-cooperative patients, with a high risk of PA pneumonia, to reach outcomes comparable to lower risk patient with a good state of alertness and a good PEF.

Since EFA® does not require an active collaboration or effort by the patient and can be easily self-managed independently at home, it could be a valid non-invasive strategy to keep clear the airways and reduce the PA risk in bedridden dysphagic non-cooperative patients with ineffective cough. Results are encouraging and support further research aimed to better address the evidences of EFA® role in the management of dysphagia.

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