



SIMEOX-THERAPY AT HOME

Patient survey on the use of Simeox at home in the treatment of cystic fibrosis (CF)

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Introduction

Simeox is a new medical device that helps patients with respiratory diseases to liquefy and mobilize bronchial secretions in the lungs and transport them to the central airways.¹ This enables a gentle secretion removal with minimal coughing. Simeox is applied while the patient is relaxed and the therapy requires less force compared to other devices, e.g. (O)PEP (Oscillating Positive Expiratory Pressure) devices. The basic methodological principle is based on intra-thoracically applied vibration (or "oscillating") generated by a pneumatic signal from the device. This vibration influences secretion clearance, like other vibrating/oscillating devices, through three modes of action²:

1.

Effect on the rheology of the secretion, i.e. the molecular structure of the secretion is changed and the viscoelasticity decreases ("liquefaction").

2.

The flow fluctuations or the repeated acceleration of the respiratory air flow ("stop-and-go mechanism") causes shearing of the secretion from the bronchial walls.

3.

The beat of the cilia in the airways is effectively supported and thus promotes the transport of secretions into the central airways.

The device is commonly used as part of chest physiotherapy exercises, often in combination with autogenic drainage. The studies (for indications like CF, bronchiectasis, COPD) published to date show, among other things, that improvement in FEV1 and FVC can be achieved by Simeox therapy.^{3,4,5} It was shown that the expectorated amount of secretion was increased⁵ and the symptom burden was reduced^{3,4}. A significant effect in the distal lung areas (MEF25) was also demonstrated⁶ and diaphragmatic mobility was shown to increase.⁷

In Germany and Austria, the Simeox device has been prescribed for home use since about two years, and the costs are covered by statutory and private health insurances. Due to the high interest of cystic fibrosis centers in

the Simeox therapy, many cystic fibrosis patients have such a device for home use.

The aim of this survey was to summarize the experiences of CF patients who use the Simeox device at home. Of particular interest was how the therapy is integrated into others, especially physiotherapeutic treatment contexts. A new, very effective medication has been available for a large proportion of cystic fibrosis patients for several months: Kaftrio. This triple combination CFTR modulator therapy shows a very positive effect on lung function and mucociliary clearance in most patients. The influence of this new drug on home respiratory physiotherapy and the use of airway clearance techniques (ACT) devices (incl. Simeox) were part of the survey.

¹ More detailed information on the manufacturer's website www.physioassist.com.

² Ref. Weise, S., P. Kardos, D. Pfeiffer-Kascha und H. Worth: Empfehlungen zur Atemphysiotherapie, 3. Auflage, Empfehlungen der Deutschen Atemwegsliga e.V., München-Orlando, 2019: p. 4-7. Arbeitskreis Physiotherapie des Mukoviszidose e.V.: Leitfaden Physiotherapie, Physiotherapie bei Mukoviszidose - Cystischer Fibrose, 4. Auflage, Bonn, 2008: p. 15, 76, 87.

Morin, L., D. Marino und A. Mithalal: Physiological effects of Simeox Airway Clearance Device in healthy adults, ERS ePoster Sept. 2020.

³ Ref. K. Iwan, D. Klatka, A. Gladzka, L. Morin, P. Sliwinski: Benefits of Simeox airway clearance technology in non-CF patients with bronchiectasis, ERJ September 2018, 52 (Supplement 62).

⁴ Ref. F. Mihaltan, L. Morin, C. Borcea, A. Costantin, A. Pahontu, L. Marinescu, V.C. Cosei: Effects of a new Airway Clearance Technology versus manual physiotherapy in COPD, ERJ September 2018, 52 (Supplement 62).

⁵ Ref. V. Kolek, P. Jakubec, J. Doleželová, L. Morin, J. Kuja: Feasibility and Safety evaluation of Simeox Airway Clearance Technique in patients with Bronchiectasis, ERJ September 2019, 54 (Supplement 63).

⁶ Ref. P. Sliwinski, D. Klatka, A. Gladzka, L. Morin, K. Iwan: Benefits of SIMEOX airway clearance technology in non-CF patients with bronchiectasis, ATS Dallas Mai 2019.

⁷ Ref. Schmidt H., M. Toth, C. Käppler-Schorn, U. Siebeneich, S. Bode, D. Fabricius. Late Breaking Abstract - Short-term effects of a novel bronchial drainage device in Cystic Fibrosis patients, Virtual International Congress of European Respiratory Society 2021

Methodology

The survey was conducted as an online survey. Patients who use Simeox at home were contacted via the home care providers (medical device dealers). They contacted the patients they had supplied with the Simeox device and asked them to participate in the survey. If they were willing to participate, an appointment was made with the patients. They then received a web link to access the standardized online questionnaire.⁸

- Out of 40 patients contacted, 31 participated in the survey, thus 31 complete interviews were included in the analysis. Selection criteria were the confirmed diagnosis of CF and the availability of Simeox at home.
- Only one patient did not take part in the survey because the device was no longer needed due to the fact that she was largely symptom-free after starting Kaftrio therapy.
- The interviews were conducted anonymously, i.e. no data was collected that would allow to identify the participants. For a large part of the interviews, the participants had the opportunity to get in touch with an interviewer available by telephone in case of questions.

*Online survey:
Simeox therapy at home*

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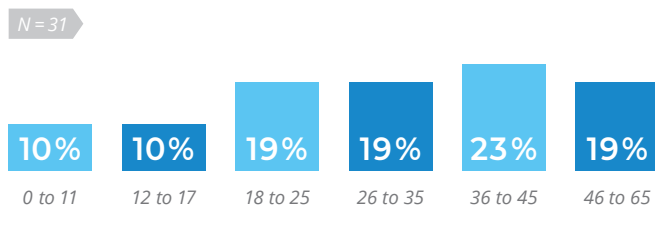


⁸ The survey instrument can be requested via kontakt@physio-assist.de or from the authors.

Respondent profile

Approximately 60 % of the respondents were female CF patients, and approximately 40 % were male. Adult patients are clearly overrepresented compared to the total population (cystic fibrosis registry)⁹. The age structure is consistent with the expectation that patients with more advanced stages of the disease are particularly dependent on additional airway clearance therapy with Simeox.

Figure 2
Gender distribution
(in years)



The FEV1 value (Forced Expiratory Volume in 1 Second, in % of the predicted value) was asked as an indicator of lung impairment. This was highly variable among the participants and corresponds approximately to the average lung function parameters of the corresponding age groups.¹⁰

- It should be noted that in some cases, FEV1 was significantly increased by intensified therapy and in particular by their Kaftrio therapy, i.e. the value was originally or temporarily lower.

Figure 1
Gender distribution

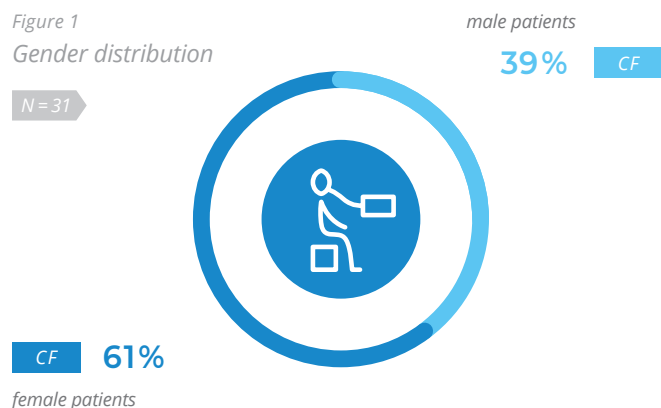
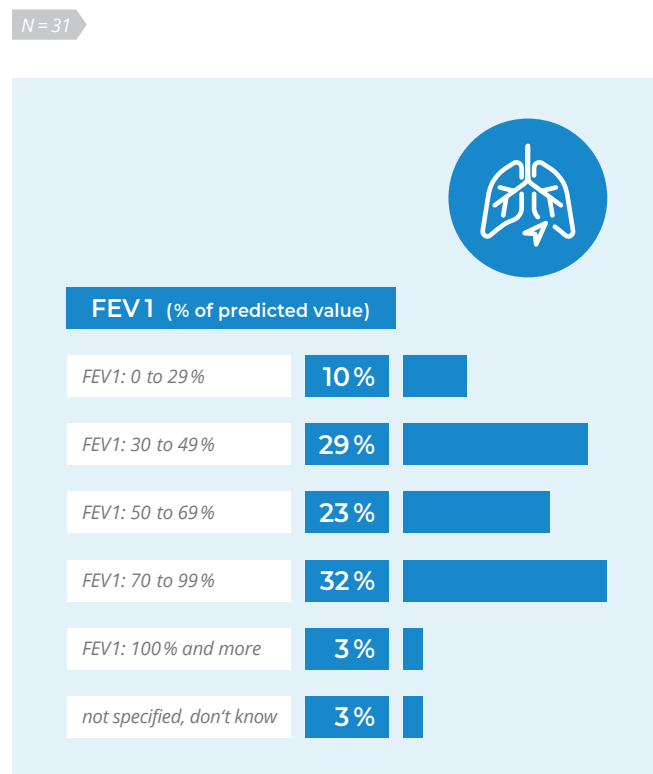


Figure 3
FEV1 distribution



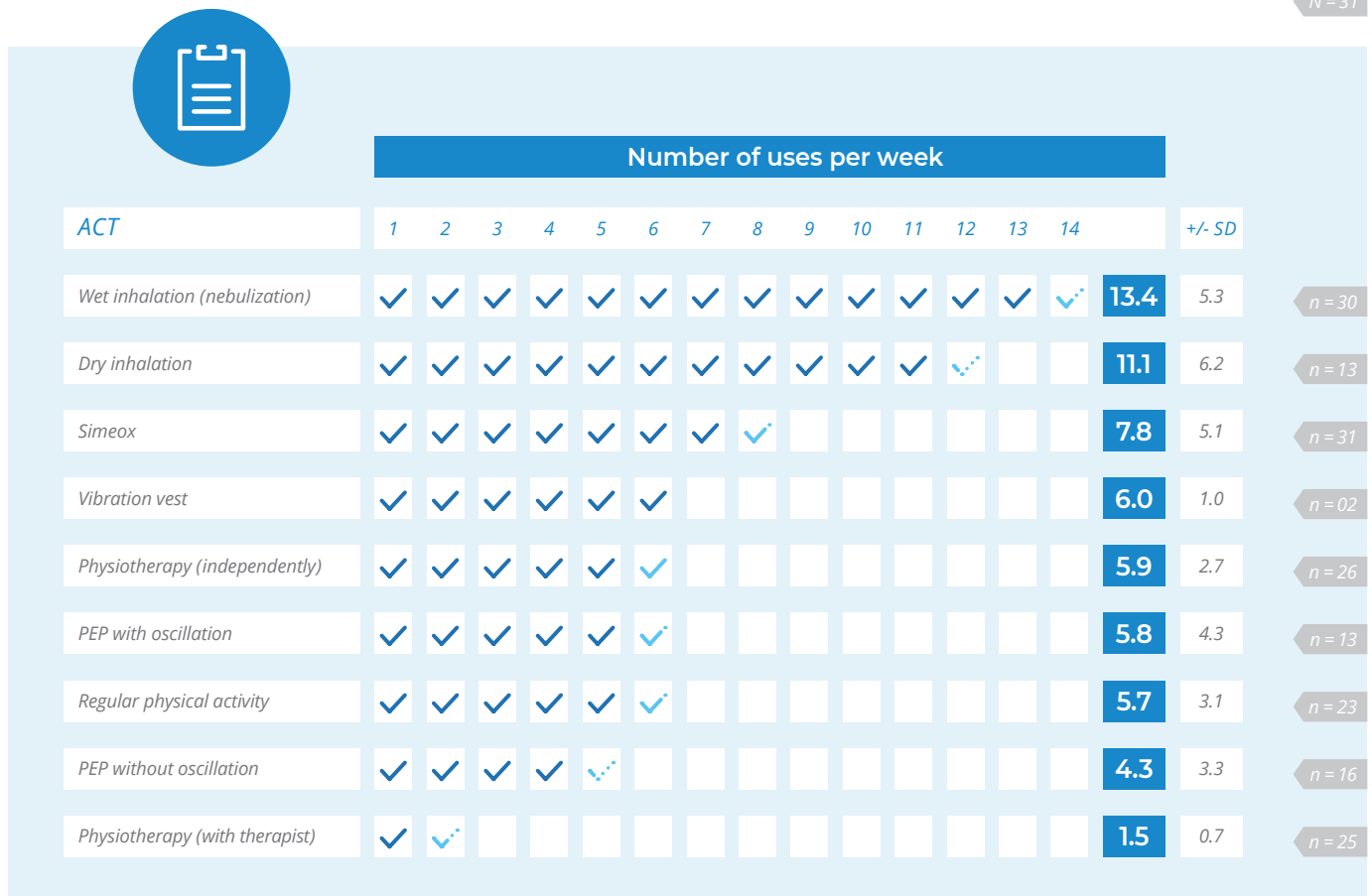
⁹ Ref. Nährlich, L., M Burkhardt und J. Wisniok: Deutsches Mukoviszidose-Register 2019: Berichtsband 1. Mukoviszidose e.V. und Mukoviszidose Institut gGmbH, Bonn, 2020: p. 10.

¹⁰ Ref. Nährlich, L., M Burkhardt und J. Wisniok: Deutsches Mukoviszidose-Register 2019: Berichtsband 1. Mukoviszidose e.V. und Mukoviszidose Institut gGmbH, Bonn, 2020: p. 21.

Therapy used

Respondents use a wide range of treatment options for airway clearance. Wet inhalation is the most commonly used, averaging about 2 times daily. Most days, on average, Simeox, independent physical therapy, PEP devices, and physical activity are used as ACTs. On average, therapy is provided 1.5 times per week in conjunction with physical therapists in the office or at home. These therapy frequencies show that the patients are overall very therapy-adherent.

Figure 4
Average use of
ACT options per week
N = 31



Please consider that the number of responses is particularly low for vibration vests.

Experiences with Simeox

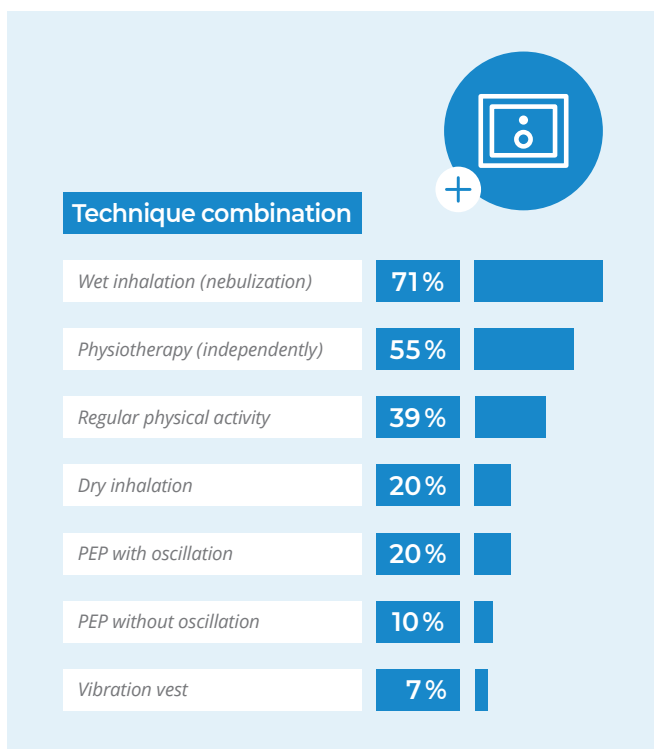
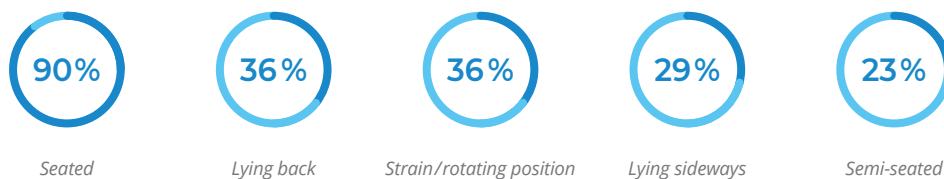
Two aspects of the therapy with Simeox were particularly interesting. Firstly, the significance and context of use, and secondly, the effect and influence on therapy satisfaction.

- > Simeox was used once daily by most patients, on average 6.4 times per week, with a range of 2-18 uses per week. The average time of Simeox use was 7.8 months - with a range of 1 to 20 months.

Patients applied Simeox in various body and stretching positions. The primary position was the upright position. Aids such as nose clips (3%) or chest straps (16%) were used only very rarely.

Figure 5
Body position during Simeox therapy
(multiple answers possible)

N = 31



- > Most patients combine Simeox therapy with other therapy options. The vast majority use Simeox in close temporal succession to wet inhalation (71%). Autonomous physiotherapy exercises (55%) and other physical activity to support secretion mobilization (39%) are also combined with Simeox therapy. The low proportion of PEP/OPEP device application combined with Simeox may indicate that Simeox is often used as a substitute for these devices when this therapy is ineffective or too exhausting for patients.

Figure 6
Therapy options used in combination with Simeox

N = 31

> Satisfaction with Simeox is extremely high. On a scale from 1 (strong disagreement) to 10 (strong agreement), the average value for agreement with the statement: "I am very happy to have the Simeox device at home" was 9.9. This high level of satisfaction is obviously due to its high effective-

ness and ease of use: Especially the mobilization in distal lung areas (9.4), the lower effort (9.1) and the therapy efficiency (9.0) were highlighted. In addition, respondents agreed to the statements, that the device and accessories are easy to assemble (9.6) and easy to use (9.5).



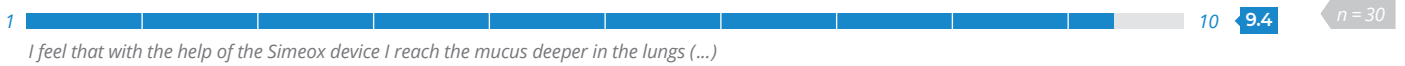
Figure 7
Level of agreement with Simeox statements

N = 31

Application



Effect



Satisfaction



The Net Promoter Score (NPS – "On a scale of 1 to 10, how likely is it that you would recommend Simeox to other CF patients?"), an established indicator of product user satisfaction, is a respectable 90 (out of a maximum of 100).

★★★★★★★☆☆ 90/100

In the summary open questions, the respondents particularly emphasized that therapy with Simeox is very effective, is less time consuming and less strenuous. The ease of use was also positively emphasized. The size and volume of the device, as well as the plastic waste produced when disposing of the consumables, were noted as areas for improvement.

Kaftrio and Simeox

Figure 8
Use of modulator therapy Kaftrio

N = 30



Yes 60%

Kaftrio (Trikafta)

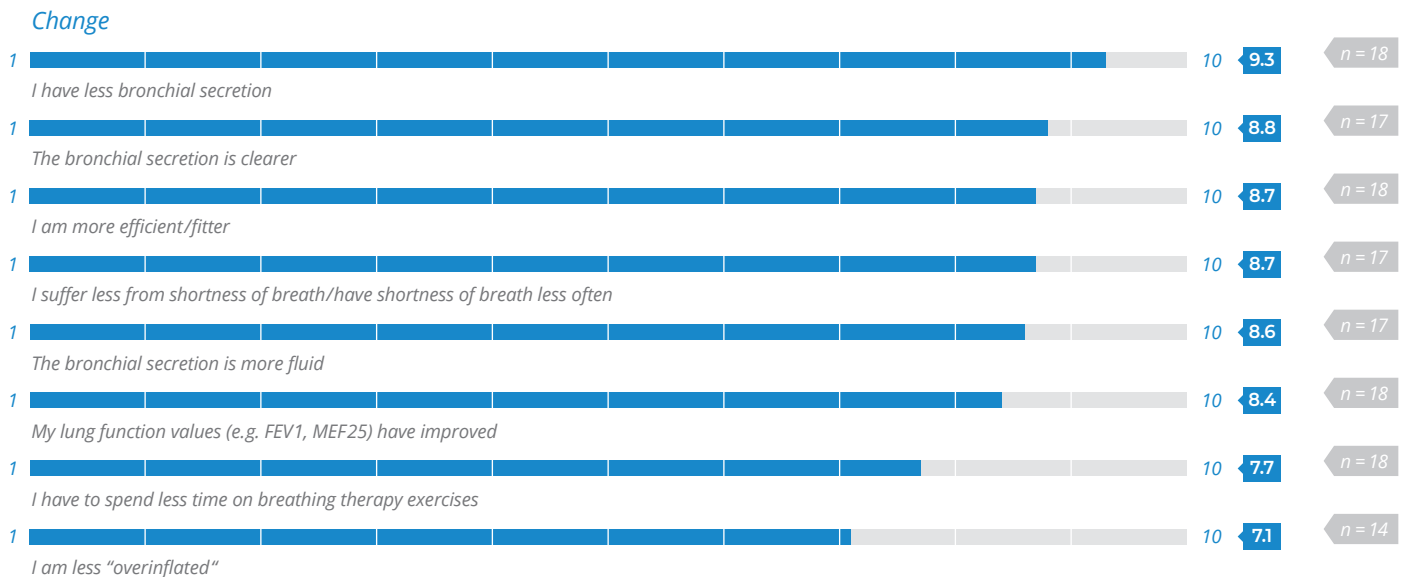
non or others

60% of the Simeox users surveyed had been taking Kaftrio for an average of 8.3 months (minimum 2 and maximum 18 months).

Of particular interest here was what changes had occurred as a result. On a scale of 1 (not at all) to 10 (very much improved), there was a clear improvement in relevant respiratory factors and an influence on secretion clearance.

Figure 9
Observed changes due to Kaftrio

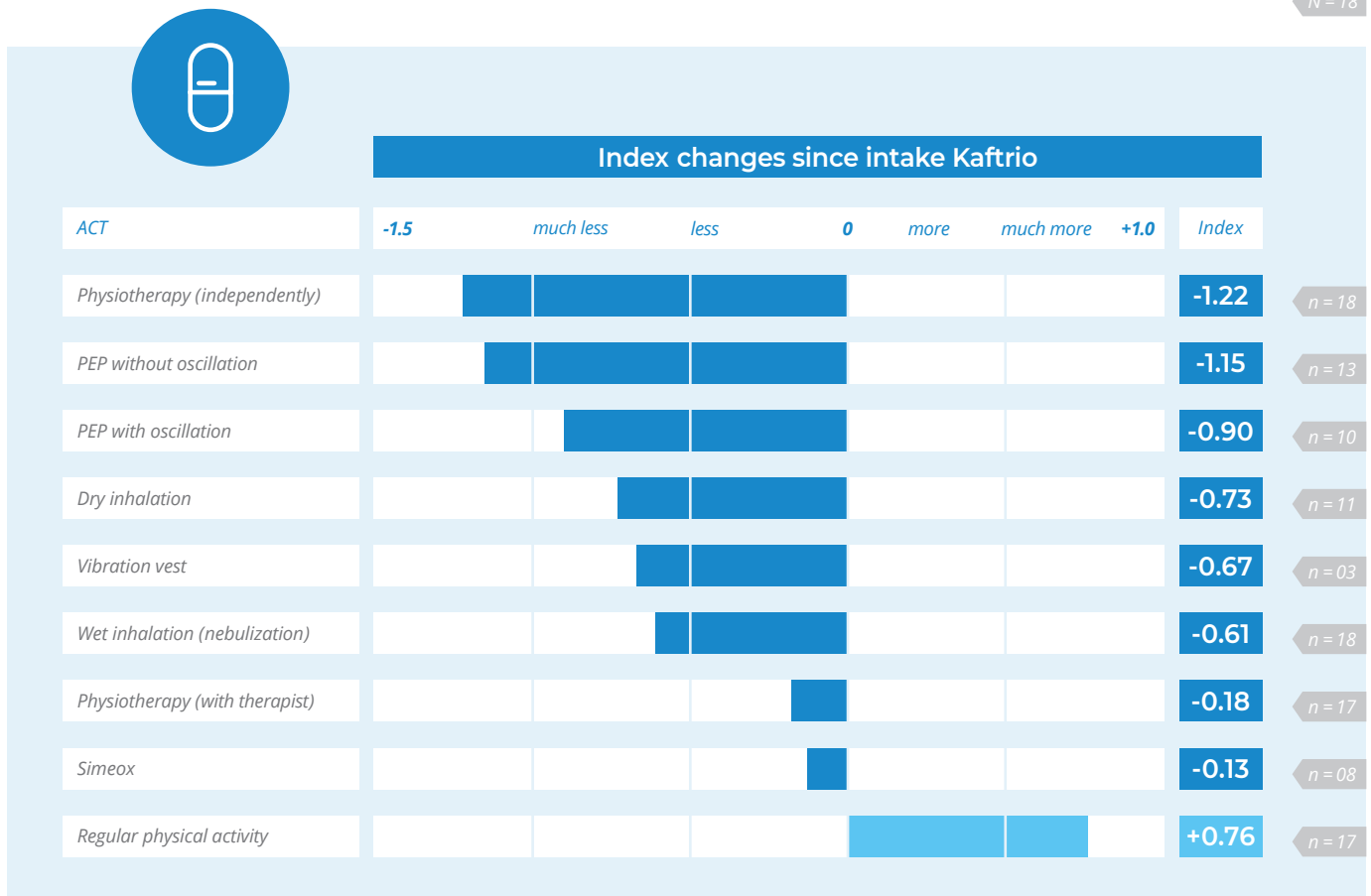
N = 18



Such an improvement raises the question of the extent to which these positive effects of Kaftrio therapy have affected the use of remedies and aids. Occasionally, patients who are convinced of the effectiveness of Kaftrio report that they may be able to do without further secretion clearance therapies.

Figure 10
Changes in therapy habits by/after Kaftrio

N = 18



- > The positive influence of Kaftrio obviously had an influence on the frequency of therapies used by the patients interviewed here, in particular on the breathing therapy exercises performed independently and PEP devices without oscillation. Both were used significantly less. Slightly smaller decreases were recorded for OPEP and moist inhalation (dry inhalation and vibration vest small numbers of cases!).
- > According to the respondents, the use of physiotherapy in the practice as well as the use of Simeox remained

about the same intensity as before the start of Kaftrio therapy. This may be interpreted as an indication that the focus is on therapy options that are particularly efficient and effective in terms of time.

- > It is gratifying that independent physical activity as a method of mobilizing secretions has increased significantly. The patients felt fitter and thus able to engage in sporting activities. This is also reflected in the evaluations of the open questions at the end of the questionnaire.

- > In ten patients, Simeox therapy had only begun after they had started taking Kaftrio. This means that it was not possible to determine whether the use of Simeox had changed as a result of Kaftrio, but rather what the decisive reason was for starting additional Simeox therapy despite the obviously already good therapeutic effect of Kaftrio.

The reasons are very diverse, also because this question was asked as an open question. One focus of the mentions is on mobilizing the distal secretion, which cannot be mobilized with other aids. *(Translated statements, partly shortened)*



“Of all devices, Simeox dissolves the secretions best.”

“To mobilize old solid secretion, I don’t have the strength for ‘normal’ devices and I get pressure headaches very quickly when using them, which I do not have with the Simeox.”

“Simeox helped to reduce the hyperinflation, the more liquid secretion can be mobilized better with Simeox, MEF25 improved significantly again with Simeox.”

“With Simeox, I’m less tense and I need less strength.”

“The mucus loosens very well and you can cough up quite a bit from deep down.”

“Through normal therapy with the PEP mask, I (note: the airways) become narrow.”

“I reach deep airways and mobilize twice as much secretion and I also mobilize the chest.”

From these responses, it can be concluded that some of the patients under Kaftrio continued to have secretions in their lungs and that these were particularly difficult to mobilize. Simeox was able to help these patients further improve their state of health by mobilizing secretions more effectively.

Conclusion

- > Simeox users tend to be older and in an advanced stage of the CF disease. They use a variety of therapies for mucociliary clearance. In particular, Simeox is often combined with inhalation therapy.

- > The users are extremely satisfied with their Simeox therapy. The release of sticky mucus in the small airways, the reduced effort as well as the therapy efficiency are the key benefits.

- > The use of Kaftrio had very positive effects on general condition and respiratory symptoms. However, the use of Simeox and the use of chest physiotherapy treatments remained unchanged with Kaftrio, whereas the use of many other ACTs decreased.

- > From the patients' point of view, Simeox is an important and helpful complement to Kaftrio and other ACTs. The significant improvement of respiratory factors by Kaftrio could be increased by the additional use of Simeox, because e.g. distal and difficult to mobilize secretions could be eliminated. This applies both to patients who first used Simeox and then Kaftrio, and to those who used Simeox in the reverse order.



High satisfaction



Therapy efficiency



Loosening of stuck secretions



Improved general condition



Reachability of the small airways



Helpful addition to Kaftrio



Reduced effort





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Read the instructions in the user manual carefully before using the device.

