Air Liquide HEALTHCARE

A prospective observational study assessing the performance of a new nasal mask used for positive airway pressure at home

Clinical study performed by ICADOM (research organization specialized in clinical investigation at home; n° 2013/4555.) on behalf of Air Liquide Medical Systems SA

Protocol available here:
https://clinicaltrials.gov/ct2/show/NCT04925739

Contact sponsor:
Dr LEBRET Marius, PT, PhD. marius.lebret@airliquide.com

International clinical practice guidelines and clinical evidences regarding mask selection in CPAP and long term NIV

"for the routine initiation of PAP therapy in adults with obstructive sleep apnea, clinicians should generally use nasal [...] mask interfaces".

American Academy of Sleep Medicine practice guideline, J Clin Sleep Med, 2019

"Oronasal masks are the most used interface for the delivery of home NIV in patients with OHS and COPD however, there is no difference in the efficacy or tolerance of oronasal or nasal masks."

"the choice of interface is mainly driven by patients' preferences, team expertise and habits"
Lebret M, Léotard A, Pépin JL et al. Thorax, 2019

"Patient participation in mask selection: patients and partners should be involved in [...] a self-management model [...] and mask-fitting considerations: time and effort should be spent during initial mask fitting."

Official American Thoracic Society Workshop Report, Ann Am Thorac Soc, 2020

Introduction

Air Liquide Medical Systems has developed a mask, the Alnest N1 Silent, that aims to improve comfort and ease of use for the patient. **This new mask is equipped with a new generation headgear with adjustment indicators to assist the patient in fitting the mask.** Optimal headgear fit is a prerequisite for comfort during treatment, as it reduces unintentional leakage. In addition, this nasal vented mask has a "silent" intentional leak port onto the elbow, which significantly reduces the noise caused by intentional leakage.

Objectives

To evaluate the impact of Alnest N1 Silent on CPAP-naive patients with OSA after 30 days of treatment regarding the following outcomes:

- Treatment adherence
- Rate of CPAP failure
- Unintentional leakage
- Related side effects
- Patient's comfort
- Patient's satisfaction

Methods

Patients were recruited from a homecare provider based in the Grenoble Area. French Ethical Committee approved the study (CPP Nord Ouest III, N° IDRCB : 2021-A01510-41).

Patients were installed with the same automatic-CPAP device set at 6-14 cmH_2O and a Alnest N1 Silent mask (Air Liquide Medical Systems) in routine care. Specific non-inclusion criteria were blocked nose (NOSE>50/100) and craniofacial abnormalities preventing the use of a nasal mask.

At the **30 days endpoint visit**, patients completed self-questionnaires regarding comfort and satisfaction. Routine care data were collected such as Epworth Sleepiness scale questionnaires (collected at inclusion too), CPAP compliance, therapeutic pressure and leakage from the CPAP built in software.

Analysis was performed on an intention-treat basis. Therefore, any patient who changed his mask or stopped using his CPAP before the 30 days endpoint was analyzed by taking into account the data collected at the time of the mask change or treatment discontinuation.

Results

70% of patients were still using Alnest N1 Silent after 30 days of CPAP treatment

75% of patients are satisfied with the mask*

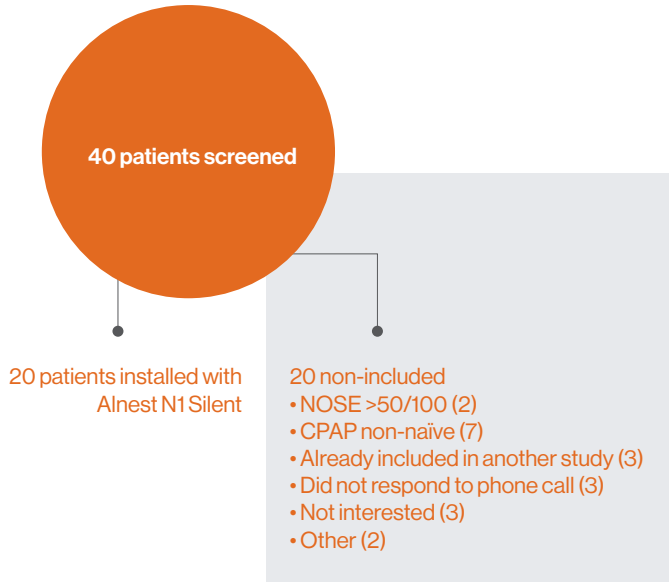


Figure 1.
Flow chart of the study

Table 1.
Baseline data at CPAP initiation Parametric variables are presented using mean and standard deviation; non-parametric variables are presented using median, 25th and 75th. Categorical variables are presented as percentages.

Age (years)	53 [50-66]
Female (%)	35
BMI (kg/m²)	32 (5.8)
Epworth Sleepiness Scale at installation	8 (4.7)
Mask sizes (%)	• S size (10) • M size (55) • L size (35)

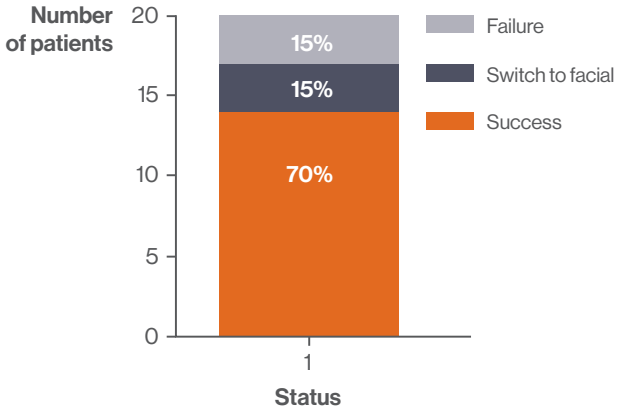


Figure 2.
Treatment status at the endpoint visit (30 days).
Patients still using Alnest N1 Silent were categorized as "success"; patients using another nasal mask who discontinued treatment entirely were categorized as "failure"; patients who switched to a facial mask were categorized as "switch to facial". Noteworthy: "success" can include patients with a mean adherence at 30 days inferior to 4 hours/night.

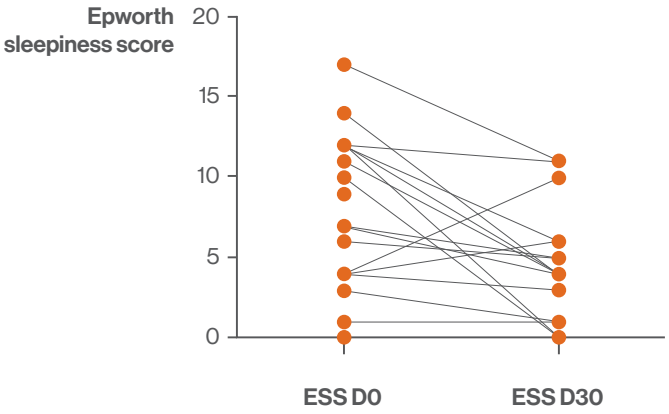


Figure 3.
Evolution of the Epworth Sleepiness Score for each patient between the CPAP initiation and the endpoint visit (30 days).

* The overall satisfaction rate on a scale of 0 to 100 was set at 70/100.

Mean (SD*) adherence at 30 days was 4 h 54 (2 h 54) minutes.

55% of patients had a mean adherence superior to 4 hours.

Technican extra visits at home during the follow-up

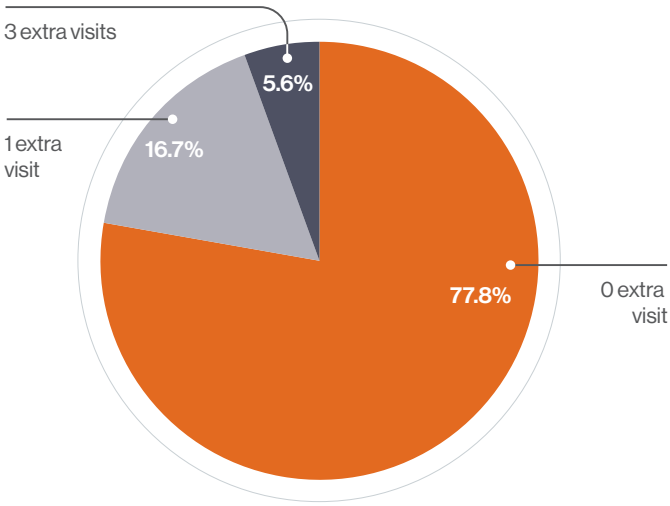


Figure 4.
Number of extra visits for each patient. Extra visits were made on patients' demand. Data was missing for 2 patients.

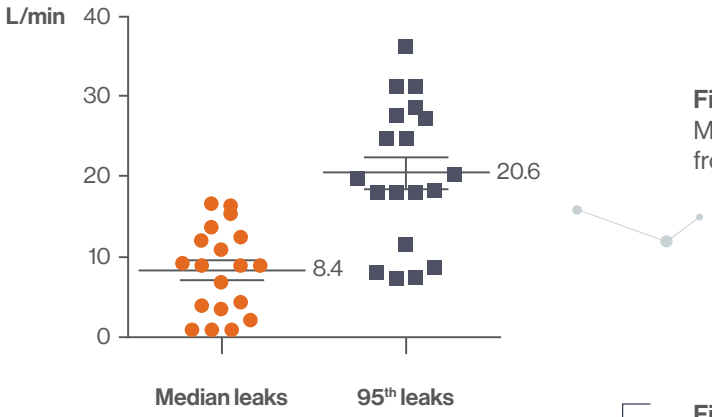
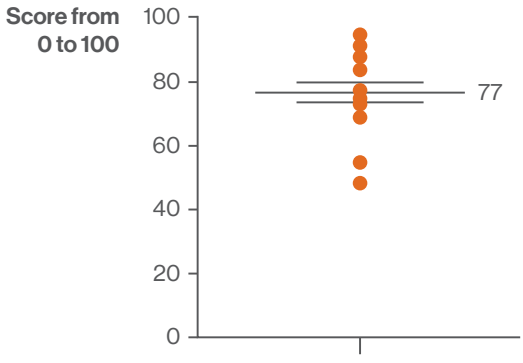


Figure 5.
Mean and 95th centile leakage in l/min over the period obtained from the device built in software.

75% of patients are satisfied with the Alnest N1 Silent*

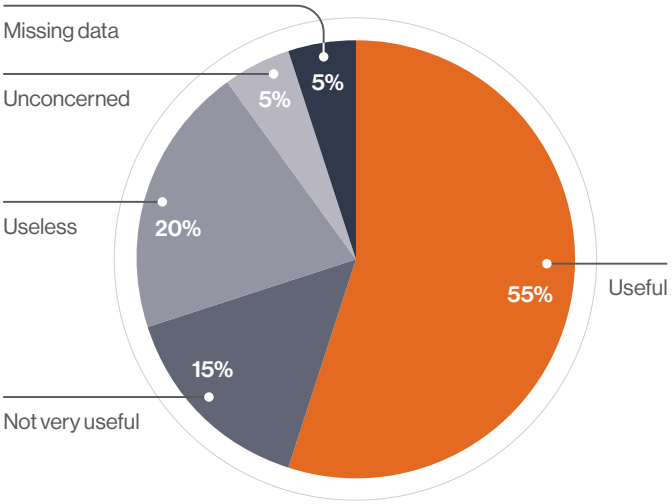
Figure 6.
General satisfaction rate ranging from 0 to 100.
This score is a consolidated score made from 8 questions answered by the patients. Each question addressed a particular aspect of the mask (general confort, cumbersomeness, leakage, noise, skin discomfort, easiness to use, easiness to disassemble or assemble).



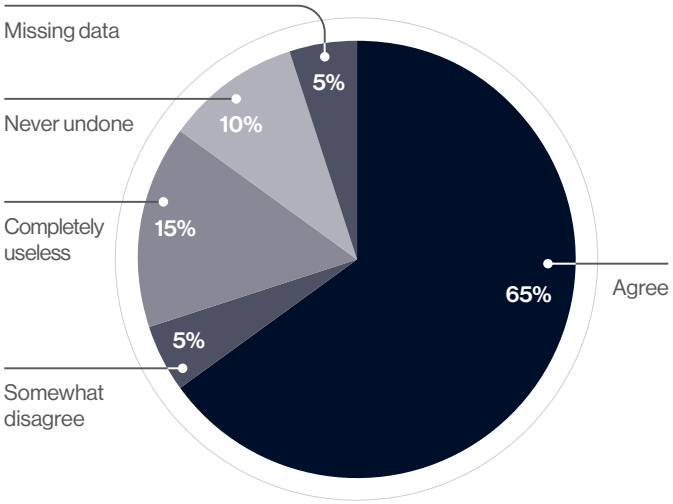
* SD: standard deviation.

* The overall satisfaction rate on a scale of 0 to 100 was set at 70/100.

Rate the usefulness of the numerical landmarks placed on the headgear



Does in/out colors helped to distinguish inside/outside of the headgear?



Figures 7a and 7b.
Patients' feedback regarding the UNIVEO™ DELTA headgear. The UNIVEO™ DELTA headgear is the headgear provided with the mask Alnest N1 Silent.

Verbatim

"I recommend the use of this mask, it is really useful"

Conclusion

- After 30 days of treatment with the mask, the success rate was high (70%), hence we can consider that the Alnest N1 Silent mask fulfilled the main requirements expected for a first intention nasal mask.
- Adherence rate at 30-days was good and comparable to what is seen in research studies (Weaver TE et al. 2008).
- A systematic review of 66 trials published between 1994 and 2015 found a weighted average adherence of 4.5 h per night which is consistent with the adherence reported in this cohort (Rotenberg BW et al. 2016).

Manufactured by

AIR LIQUIDE MEDICAL SYSTEMS S.r.l
Via Bisceglie, 66 - 20152 Milano (MI) - ITALY
PLANT: Via dei Prati, 62 - 25073 Bovezzo (BS) - ITALY
Tel. +39 030.201.59.11
Fax +39 030.209.83.29

Distributor contact

AIR LIQUIDE MEDICAL SYSTEMS S.A.
Parc de Haute Technologie
6, rue Georges Besse
92182 Antony Cedex
France

https://medicaldevice.airliquide.com/
Mail: dl-frtaema-src-export@airliquide.com

Hotline ALMS: +33 179 51 70 01

Study conducted by

IC@dom. INVESTIGATION CLINIQUE A DOMICILE

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Alnest N1 Silent is a reusable nasal mask with calibrated exhalation orifices (Vented) intended to be used at home or in a hospital setting by a single adult patient weighing over 30 Kg, who have been prescribed with a non-invasive positive pressure ventilation therapy (NIPPV), e.g. continuous positive airway pressure therapy (CPAP) or Bilevel positive airway pressure therapy (BiPAP).

Medical device class IIa CE0051. Please read the user manual.

YN23197_IND 1_2023-03_Mask_EN_Clinical study ALNEST N1Silent_ - Design CHANH THI