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# Compliance in Sleep Apnea Therapy: influence of home care support and pressure mode

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**Running title:** **Intensive Support for CPAP Compliance**

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**Abstract:**

Question: Continuous positive airway pressure (CPAP) is an effective treatment for obstructive sleep apnea syndrom (OSAS), but therapy adherence is often low. We tested the hypothesis that CPAP-adherence and clinical outcomes can be improved by either using an autoadjustingCPAP (APAP) device or an intensive support.

Measurements: Controlled parallel group study with 100 newly diagnosed OSAS patients, randomised into 4 groups (n=25): standard or intensive support plus APAP or CPAP. Intensive support included education and monthly home visits for 6 months. Clinical outcome was monitored by polysomnography at CPAP initiation and after 3 and 9 months, compliance data were downloaded from the CPAP devices.

Results: After nine months, intensively-supported patients returned for follow-up in 88% vs 68% in the standard-support-group. Mean daily usage ([mean±SEM] 5.7±0.2h intensive support vs 4.6±0.4h standard support), percentage of days used (80.4±2.8% vs 57.0±5.9%) and proportion of individual sleep time (80.6±3.2% vs 64.9±6.2%) were also higher. There was no significant difference between APAP or CPAP, (daily usage[APAP vs CPAP] 5.2±0.4h vs 5.1±0.3h, percentage of days 67.9±5.0% vs 69.2±4.9%, proportion of sleep time 72.5±5.0% vs 72.1±5.2%), but retention rate was higher with CPAP.

Conclusion: Intensive support after CPAP initiation rather than the application of APAP, increased therapy adherence.

INTRODUCTION:

Obstructive sleep apnea syndrome (OSAS) is a major public health burden, with a wordwide prevalence of 2-4% among the adult population [1]. OSAS is associated with excessive daytime sleepiness, cognitive dysfunction, impaired quality of life, hypertension and an increased cardiovascular morbidity and mortality [2]. Continuous positive airway pressure (CPAP) is an effective treatment for OSAS symptoms also decreasing cardiovascular morbidity and mortality [3] [4] [5] [6].

However the effectiveness of this symptomatic therapy mainly depends on regular use. The use/comfort of CPAP therapy may be limited by side effects such as e.g. mucosal irritation, mask dislodgement, mask leak or difficulty in exhaling, which may critically impair compliance [7] [8] [9] [10] [11] [12] or lead to discontinuation of therapy: 23% of patients quit CPAP within 5 years, most of them during the first year [13]. In other publications, discontinuation rates ranged from 8 [11] to 46% [14].

Most of the side-effects are associated with the airflow generated by the CPAP device, and tend to worsen with higher pressures or airflow rates, respectively. The pressure required to achieve airway patency often varies throughout the night, i.e. it may be higher during REM sleep or supine position.

AutoCPAP (APAP) devices were developed for continuous adjustment of pressure, which yields a lower mean pressure needed to achieve airway patency: Pressure is increased when airflow limitations or an increase in upper airway resistance are identified, whereas pressure is decreased when the airway is open. However, so far no significant improvement of comfort and compliance have been demonstrated, while the clinical outcomes seem to be similar for both pressure modes [10] [15].

Intensive patient support is usually aimed at early minimizing adverse factors and focussing patients' awareness on the necessity of the treatment and the benefit eventually derived from it. The first few weeks seem to be crucial for patients' coping

with the disease and their acclimatization to therapy [16] [17], and thus for long-term compliance. Hence most of the interventions studied were focussed on this period of time. Problems caused by mask, airflow or an increase in pressure can be addressed by re-adjustment of the interface and/or the CPAP device e.g., whereas prejudice, embarrassment or technical problems in dealing with the equipment are a possible target to behavioural/educational measures. Investigators have used education about disease and therapy by different media [18] [19], and a closer monitoring by means of phone calls, letters [16], or telemedicine [20]. One study was based on home visits and could show an increase in the hours of use, with an improvement in subjective daytime symptoms and mood [18], however more reliable clinical outcome parameters regarding the disease severity such as the apnea-hypopnea index (AHI) were not compared.

The primary aim of this study was to test whether an intensive support of OSAS patients during the first 6 months of CPAP therapy can enhance CPAP adherence and improve clinical outcomes compared to standard support. In addition, the effectiveness and compliance of auto (APAP) and fixed pressure therapy was compared. It is the first long-term interventional study with 100 patients being followed over nine months. Four different surrogate parameters for compliance and a set of clinical parameters which allows for an estimation of cardiovascular impairment as well as sleep fragmentation and daytime somnolence were used.

**METHODS:**

**Study design:**

A total of one hundred patients (78 males and 22 females, age 57 ± 12 yr [mean ± SD]; BMI 31 ± 5 kg/$m^2$) with newly diagnosed OSAS were enrolled (inclusion criteria: AHI ≥15, with or without corresponding daytime symptoms). Exclusion criteria were as follows: 1) any global respiratory failure 2) central sleep apnea syndrome and 3) any severe mental or psychological impairment. Before enrolment, all patients gave their written informed consent and answered a questionnaire regarding daytime sleepiness (Epworth Sleepiness Scale, ESS). The study was approved by the local ethic committee of the Albert-Ludwigs-University of Freiburg.

Patients underwent standard diagnostic overnight polysomnography using Heinen and Löwenstein SIDAS (Herrsching, Germany) or Jaeger Sleeplab 1000 (Würzburg, Germany) polysomnography system. Sleep measurements during polysomnography included standard electroencephalography (EEG), electrooculography (EOG) and electromyography (EMG). Nasal airflow and oxygen saturation were measured by thermistor and pulse oxymetry, respectively, and patients were monitored and recorded by infrared video camera. Respiratory effort was determined by thoracic and abdominal gauges. Following polysomnography, sleep stages and respiratory events were visually analysed and edited page by page. The diagnostic night (DIAG) was followed directly by a second full-night polysomnography with CPAP therapy (THER_INI) during which the CPAP-adjustment was performed by attended autotitration (pressure-limits 6-14 mbar). Thereafter patients were allocated to following groups: standard support and APAP therapy (n=25); standard support and CPAP therapy (n=25); intensive support and APAP therapy (n=25); intensive support and CPAP therapy (n=25). Fixed CPAP pressure was obtained choosing the pressure level with lowest RDI during the

polysomnography. In all four groups a further polysomnographic monitoring and interview were performed after 3 months (3M) and 9 months (9M) of CPAP treatment.

The intensive support groups were further visited by specially trained members of our Sleep Laboratory of the Department of Pneumology at 1, 2, 4, 5, and 6 months after CPAP therapy (see Figure 1). Intensive support included optimizing of the equipment such as mask fit, the use of moisturers as indicated, and an early identification of patients with low compliance, as well as educational support and counselling.

**CPAP-units:**

The CPAP device used was the AutoSet Spirit (ResMed, Sydney, Australia) which allows for switching between the conventional CPAP- and the auto-adjusting pressure mode. Furthermore, data concerning compliance (days and hrs used, total of days etc.), clinical parameters (apneas and hypopneas) as well as pressure and air leakage can be recorded, stored for up to 365 days and downloaded.

**Outcome measurements:**

Polysomnographic data were collected at the time of diagnosis and therapy initiation, after three and after nine months. These data included the AHI (total numbers of apneas and hypopneas calculated over the total sleep time), arousal-index, oxygen-desaturation-index (ODI) and sleep profiles. Data stored in the AutoSet Spirit were downloaded after each polysomnography and during every home visit. The device records the total of days, the percentage of days used, the total of hours, the daily usage in hours, air leakage episodes, the pressure delivered, the apnea-hypopnea index and the mean duration of apneas. We also obtained ESS-scores at every encounter. Compliance data were obtained as follows: Retention rate was calculated from the number of patients who returned for follow-up divided by the total number of

patients, the daily usage was calculated from the total of hours divided by the total of days used, the days the device was actually used were divided by the total of days to obtain the percentage. The portion of individual sleep time spent with appropriate mask pressure was calculated from the daily usage in hours divided by patients' self-estimated sleep time they gave at the interview. Compliance parameters were set to zero when patients did not appear for their follow-up visit (intention-to-treat).

**Statistical analysis:**

Power analysis was performed by the Department of Biometry and Medical Statistics, University of Freiburg, using PS Power and Sample Size Calculations by William D. Dupont and Walton D. Plummer. (power 0.85, $\alpha < 0.05$, 1-ß = 0.9). Statistical analysis was performed using GraphPad Prism version 4.00 for Windows, GraphPad Software, San Diego California USA. All variables were tested for normal distribution and equal variance. Means and standard error of the mean (SEM) were calculated to describe continuous variables. For all experiments, the statistical significance of differences between samples was calculated using the ANOVA, Bonferroni comparison test. Differences were considered significant if $p<0.05$. Data are presented as mean ± SEM.

**RESULTS**

**Patient characteristics:**

Patient characteristics were similar in all four groups (see table 1), and basic data such as the BMI did not significantly change in the course of the study.

**Intensive support significantly enhanced adherence to CPAP therapy, compared to standard support.**

After nine months of therapy, 88% of the intensively supported patients returned for follow-up, but only 68% of the patients receiving standard support. As shown in table 2, patients in the intensive support arm had used their CPAP device significantly more often (80.4 ± 2.8, percentage of days) between the two follow-ups. After nine months of CPAP treatment, usage was also higher (5.7 ± 0.2 hours) in terms of absolute duration, as well as related to patients' individual sleep time (80.6 ± 3.2) compared to the standard support arm (57 ± 5.9%, $p< 0.001$; 4.6 ± 0.4 h, $p< 0.05$; 64.2 ± 6.2% $p< 0.05$)

**Intensive versus standard support – clinical outcomes:**

Indices of disease severity (AHI, ODI, Arousal Index) showed no difference between the different support groups at baseline, but were significantly decreased at the start of the therapy and remained low (see table 3). ESS-scores were different at baseline, formally indicating a higher mean daytime sleepiness in the intensive support group. After nine months however, no difference could be detected between the two groups.

**APAP versus CPAP – clinical outcomes:**

The two modes were equally effective in reducing respiratory disturbances. AHI was decreased from 41.8 (±20.9) to 7.4 (±3.8) (APAP) and 45.5 (±22.4) to 11.4 (±9.2) (CPAP) respectively in the first night of CPAP treatment ($p<0.001$). There was a further reduction of the AHI in the long term either, but at no time a significant difference between the groups could be observed. Daytime-sleepiness was reduced significantly throughout the time in both groups, but the CPAP group showed higher ESS Scores (see table 4).

**APAP versus CPAP – mean pressure and compliance:**

Pmean was 1.0-1.2 $cmH_2O$ higher in CPAP, 9.2 (±1.3) $cmH_2O$ THER_INI and 9.4 (±1.1) $cmH_2O$ (3M and 9M) vs. 8.8 (±1.6) $cmH_2O$ THER_INI, 8.2 (±2.0) $cmH_2O$ (3M), and 8.4 (±1.5) $cmH_2O$ (9M), $p<0.001$ (see table 5). However, no differences in therapy adherence could be observed: There was an overall decrease in compliance in both pressure groups in the long term, in terms of the Percentage of days used as well as daily usage. APAP-patients used their device for a similar proportion of their individual sleep time as CPAP patients (see table 2).

Mean air-leakage was mainly constant in both groups with a slight decrease in the APAP group (see table 5). Changes and differences between the groups were not statistically significant, values tended to be higher in the CPAP group, though.

## DISCUSSION

This controlled parallel group trial shows that an intensive support, especially during the first few months from therapy initiation can enhance long-term adherence to CPAP in obstructive sleep apnea for up to 20%, whereas the use of autoadjusting CPAP had no such effect. It is the first home-based interventional study to follow 100 patients over 9 months, using several different parameters for compliance and clinical outcome.

Overall compliance was high in continuing users in both groups, with over 75% of days used and a mean nightly usage of over five hours. Comparable data on CPAP adherence were published before. Pieters and coworkers reported on a mean use of 5 ± 1.8 hours per night, remaining stable for two years [21]. Kribbs found an utilisation rate of 66% of the days monitored [14]. A recent study by Sucena et. al. showed an increase in compliance in continuing users in the long term with 5.35 hrs after 1 and 6.55 hrs after 10 years. 23% of patients quit CPAP within 5 years, most of them during the first year [13].

In our study, the most evident effect of the intervention was a lower drop-out-rate among patients who had received an intensive support, where compliance data were monitored closely and therapy problems could be addressed immediately. 88% of these returned for follow-up after nine months, versus 68% of patients receiving standard support, which means that more patients were kept from discontinuing their therapy by the intervention performed. This suggests that the general acceptance of CPAP as a key aspect of therapy efficiency is an important, clear-cut and perhaps more promising target for specific interventions.

Mean daily usage, the percentage of days used and the proportion of individual sleep time spent with adequate mask pressure were higher for up to 20% in the intensive support group, when analyzed on an intention-to-treat basis. However, a possible limitation of these data might be a conservative missing value imputation, which could increase the statistical error.

Notably, even the “standard support” applied to the control group was more intensive than common support at the sleep unit, with an explanation about the disease and its possible sequels, a thorough introduction to the device and equipment and a brief diurnal CPAP trial before the second polysomnography.

This effect may account for part of the high overall compliance, compared to literature [14] and has already caused difficulties in observing differences in several interventional CPAP trials [18] [22] [23] [24].

Another common problem in interventional CPAP trials is that not specific interventions but rather “packages” [25] are studied, so that the most relevant measure can not be identified distinctively. Hoy and colleagues used an intensive education, a 3-night CPAP-trial and home nursing. They reported a 40% higher CPAP use with intensive support, sustained for over six months, in terms of hours used per night. Percentage of days or other parameters of usage were not monitored [18]. Wiese et al. showed a

higher retention rate for 1-month follow-up after video education with 72.9% vs. 48.9% in the control group [19]. Chervin and colleagues performed education, phone calls and letters [16]. Our study shows the effectiveness of regular home-visits in the first six months from therapy initiation. We could not clarify in this study, whether the higher frequency of encounters or the home setting has led to a higher adherence to CPAP. A combination of home visits at therapy initiation, but for a shorter period than in our study, followed by more frequent follow-ups at the sleep units might be a feasible alternative strategy.

Other measures, such as optimizing mask-fit and educational support, were provided to patients in both groups, as mentioned above, however more frequently to the intensive support group. This may also have led to higher material costs in some patients of that group, contributing, on the other hand, to their acclimatization to CPAP. This suggests that, even if inferior to psycho-educational measures, mechanical interventions in terms of equipment optimization (moistures, different interfaces etc) at therapy initiation should also be employed when necessary, in order to prevent impairment of CPAP adherence.

In our experience, increased mask discomfort and equipment requirements, resulting in frequent interface change at therapy initiation, are the manifestation of difficulties in acclimatization to CPAP and coping in some patients. Intensive support, addressing the underlying problems and helping the patient to achieve a positive „cost-benefit-calculation“, despite all discomfort, will help to reduce these material costs. These savings, however, could be allocated to personal costs again.

Additional savings could be achieved by the delay of definite purchase of CPAP devices by health insurers until proper assessment of patient compliance.

Therapy efficiency should be monitored closely, using data storage in CPAP devices and personal supervision. This will help to identify patients at risk of abandoning CPAP

and to intervene, if necessary. Therefore, current considerations to simplify treatment and follow-up to save money in the short run cannot be supported from this “compliance”-point of view.

As to the measurement techniques applied, our set of different parameters allows for a more detailed analysis of different usage patterns and therefore yields a closer description of compliance as a construct.

Clinical outcome parameters, i.e. the AHI, as well as ESS-Scores tended to decrease continuously. This suggests some curative aspects of CPAP in the long term, because we used the values measured at defined time points which are not directly influenced by usage rates. Mean values over time could help us to detect a true continuous improvement. One possible explanation for such an effect is the reduction of mucosal oedema by minimizing vibrational trauma, which is known to account for upper airway collapsibility in part [26]. Another possible explanation is a reduction in sleep fragmentation, reflected by a further decrease in the Arousal-Index in our study, for sleep fragmentation is known to increase upper airway collapsibility [27] [28]. A decrease in daytime somnolence may also be due to a better acclimatization to CPAP and therefore less sleep fragmentation. The BMI did not change significantly in the course of the study, so weight loss cannot explain the improvements noticed in this case.

The reduction of the AHI appeared to be stronger with intensive support. Here, a direct effect of the intensive support must be postulated, rather than a statistical one through a higher compliance. In our opinion, optimizing the equipment such as mask fit, minimizing side-effects such as rhinorrhoea by the use of moistures, an early identification of patients with low compliance and again a better acclimatization to CPAP accounted for a better quality and effectiveness of therapy, also in terms of clinical outcome. ESS mean values at baseline were significantly different telling a

possible bias for compliance outcome. However, they were comparatively low in both groups, indicating that overall symptom severity was not as evident as the high RDI would have suggested. Additionally, they decreased in the same manner in both groups. Therefore, even if slightly increased or normal ESS values were considered to influence CPAP therapy adherence [11], this did not influence compliance outcomes in our study.

The clinical significance of these improvements remains unclear. A decrease in the AHI may well reflect amelioration of disease severity and hence its cardiovascular sequels through CPAP, as has been reported [3] [6]. Hoy and colleagues also demonstrated a reduction in sleepiness, better mood and improvements in reaction time. However, these parameters mainly pertain to quality of life issues. Parameters more related to intermittent hypoxia and its sequels, such as the AHI were not discussed. Therefore, more studies on long-term cardiovascular outcomes, also considering costs arising from an increased morbidity, mortality and occupational injuries are needed to confirm relevant benefits from a higher therapy adherence and an intensive support, respectively. A consistent definition of effective CPAP use in terms of hours used per night, percentage of days etc. is still lacking – "how much is enough?" [29] still remains an important question.

Second, we also compared APAP vs. CPAP. Pmean was about 1 $cmH_2O$ lower after three and nine months, as was reported for APAP before: Teschler found a 23% reduction in APAP compared to CPAP [30].

Variation of pressure in the APAP-device did not cause higher air-leaks or more arousals during sleep, i.e. the Arousal-Index was similar in both groups. However, we did not analyze the association between arousals and single pressure changes. Fuchs and colleagues found that an average of 20 % of microarousals (MA) were preceded by

a significant change in pressure (at least 0.5 mbar within 30 sec.) delivered by APAP, but the relative amount of "pressure-associated MA" was not significant in most individuals [31].

The lower Pmean among APAP-patients did not lead to a higher compliance or therapy adherence, respectively. Patients used their device for more than 5 hrs/d and for about 75% of the days during the first three months in both groups, retention rate was even lower under APAP.

In their comparison between APAP and CPAP, Randerath and colleagues also found no difference in compliance despite a lower Pmean under APAP. The duration of use was 5.25 h/d. However, 75% of the patients preferred APAP for long-term treatment at home [15]. Konermann et al. found a higher amount of nights per week with nCPAP use for more than 4 h with APAP after 6 months of therapy but without a significant difference in daily use [32]. The authors themselves state that the slightly higher patient compliance with the self-adjusting device needs further confirmation, which could not be supported by our study. Additionally, in a recent meta-analysis by Ayas et al. a similar patient adherence for APAP and CPAP was found [33]. The specific reasons for subjective preferral of APAP remain unclear. The effective reduction in Pmean is a possible explanation, but it has to be questioned whether patients have registered this reduction directly – the possibility would increase with a greater inter-individual variability of pressure throughout the night. An indirect benefit by the reduction of pressure- or airflow-associated side-effects can be assumed as a factor of influence, but these questions were not evaluated in our study so far.

As to the clinical outcomes, both CPAP and APAP were equally effective in reducing the AHI, compared to the AHI at diagnosis with even a further decrease in the long term. Parallely, daytime sleepiness was reported to decrease significantly.

APAP as a mechanical type of intervention, showed no relevant impact on compliance or clinical outcomes in the therapy of OSAS compared to CPAP. Therefore, a switch to APAP device, which are more expensive currently, cannot be recommended in general, but a more selected group of patients might benefit from an automatic adjustment of pressure. As a result, more precise differential indications for the use of APAP have to be identified. Furthermore, even the use of APAP for unattended therapy initiation at home has to be questioned, because the setting at the time of diagnosis and start of therapy – sleep unit or patients' home – also has shown to be a predictor of long-term compliance [34] [35]. However, some costs may be reduced by using APAP for attended autotitration for determination of fixed CPAP pressure.

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FIGURE LEGENDS

**TABLE 1: Patients characteristics**

*CPAP*: conventional CPAP group; *APAP*: auto-adjusting CPAP group; Data are shown as mean ± SEM

**TABLE 2: Compliance data intensive versus standard support and APAP vs. CPAP**

Merged group data (CPAP plus APAP *or* intensive plus standard support). *daily usage (h):* calculated from the total of hours (counter of CPAP device) divided by the total of days used; *percentage of days (%):*days used divided by the total of days; *hours used/sleep time:* daily usage in hours divided by patients' self-estimated sleep time given by interview. *APAP*: auto-adjusting CPAP group; *CPAP*: conventional CPAP group; *3M*: follow-up after 3 months; *9M*: follow-up after 9 months; Data are shown as mean ± SEM; *p < 0.05; **p < 0.01 between groups at the same point of time

**TABLE 3: Clinical outcomes intensive versus standard support**

Merged group data (CPAP plus APAP). *DIAG*: diagnostic polysomnography; *THER_INI*: therapy initiation; *3M*: follow-up after 3 months; *9M*: follow-up after 9 months; *AHI*: Apnea-Hypopnea Index, number of apneas plus hypopneas per hour; *ODI*: Oxygen Desaturation Index, number of oxygen desaturations >4% per hour; *ArI*: Arousal-Index, number of arousals per hour; *ESS*: Epworth Sleepiness Scale; Data are shown as mean ± SEM; $^{\#\#}$p< 0.01 compared to DIAG, same group; *p< 0.05 between groups at the same point of time

**TABLE 4: Clinical outcomes APAP vs. CPAP**

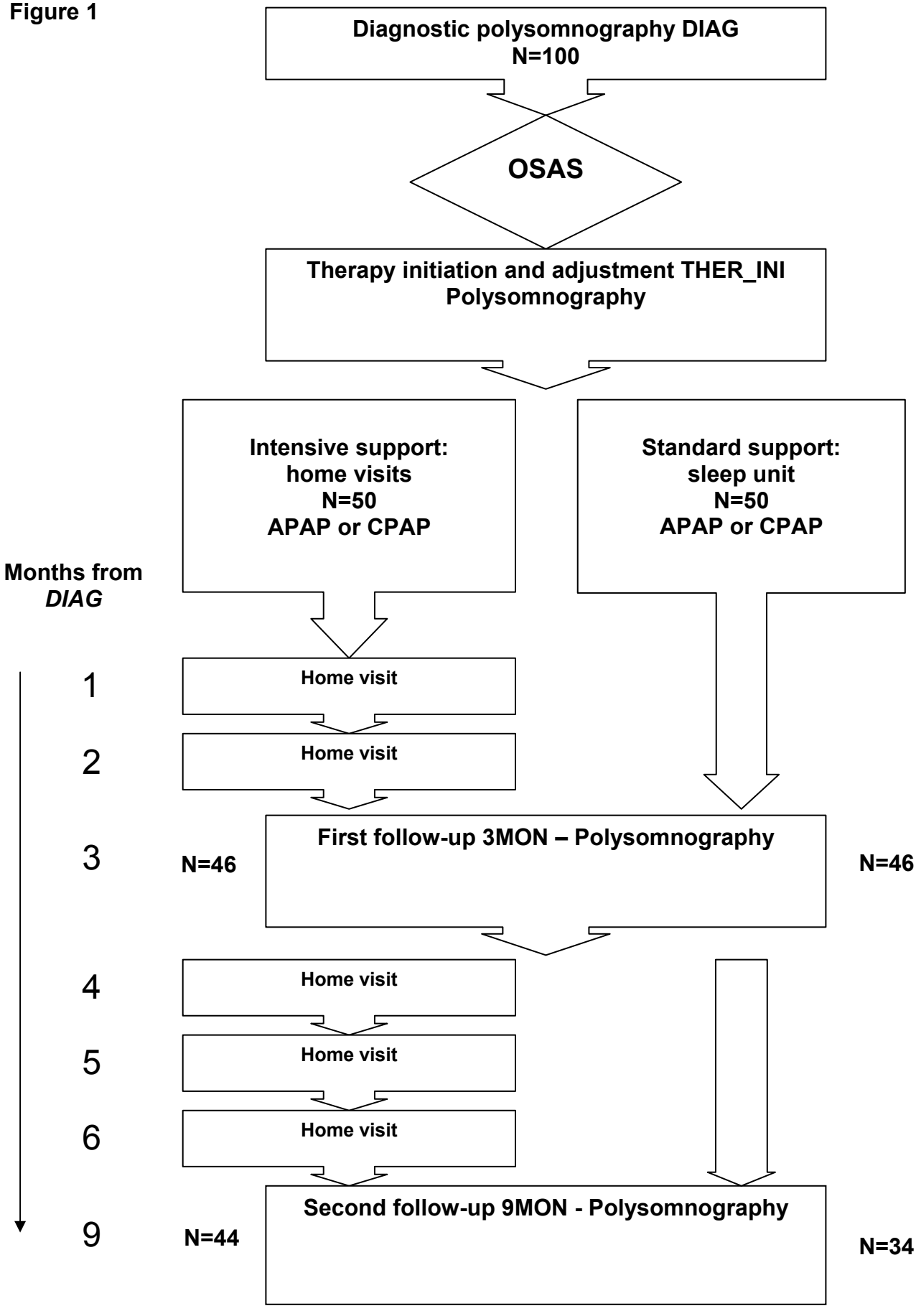
Merged group data (intensive plus standard support). *APAP*: auto-adjusting CPAP group; *CPAP*: conventional CPAP group; *DIAG*: diagnostic polysomnography; *THER_INI*: therapy initiation; *3M*: follow-up after 3 months; *9M*: follow-up after 9 months; *AHI*: Apnea-Hypopnea Index number of apneas plus hypopneas per hour; *ODI*: Oxygen Desaturation Index, number of oxygen desaturations >4% per hour; *ArI*: Arousal-Index, number of arousals per hour; *ESS*: Epworth Sleepiness Scale; data are shown as mean ± SEM; $^{\#}p < 0.05$ and $^{\#\#}p< 0.01$ compared to DIAG, same group

**TABLE 5: Mean pressure and air leakage APAP vs. CPAP**

Merged group data (intensive plus standard support). *APAP*: auto-adjusting CPAP group; *CPAP*: conventional CPAP group; *DIAG*: diagnostic polysomnography; *THER_INI*: therapy initiation; *3M*: follow-up after 3 months; *9M*: follow-up after 9 months; *P mean*: Mean positive airway pressure; data are shown as mean ± SEM; **p<0.01 between groups at the same point of time

FIGURE 1: Support protocols and course of the study*DIAG*: diagnostic polysomnography; *THER_INI*: therapy initiation; *3M*: follow-up after 3 months; *9M*: follow-up after 9 months. N = 100 patients were included, 78 completed the study.

**Figure 1**



| | CPAP plus Intensive support | CPAP plus Standard support | APAP plus Intensive support | APAP plus Standard support |
|---|---|---|---|---|
| Gender | 20 men, 5 women | 17 men, 8 women | 21 men, 4 women | 20 men, 5 women |
| Age (years) | 59.4 ± 2.1 | 57.6 ± 2.1 | 54.9 ± 2.9 | 57.8 ± 2.0 |
| Height (cm) | 172.3 ± 2.1 | 171.6 ± 2.0 | 172.0 ± 1.9 | 174.6 ± 1.9 |
| Weight (kg) | 90.5 ± 3.6 | 92.1 ± 3.4 | 93.9 ± 3.7 | 94.1 ± 3.3 |
| BMI ($kg/m^2$) | 30.5 ± 1.2 | 31.2 ± 1.0 | 31.8 ± 1.2 | 30.8 ± 0.8 |

**TABLE 1: Patients characteristics**

| | Intensive support | Standard support | Intensive support | Standard support | APAP | CPAP | APAP | CPAP |
|---|---|---|---|---|---|---|---|---|
| Time point | 3 M | | 9 M | | 3 M | | 9 M | |
| Daily usage (h) | 5.5 ± 0.2 | 5.4 ± 0.3 | 5.7 ± 0.2 | 4.6 ± 0.4* | 5.4 ± 0.2 | 5.4 ± 0.3 | 5.2 ± 0.4 | 5.1 ± 0.3 |
| Percentage of days | 82.7 ± 2.7 | 68.7 ± 4.6* | 80.4 ± 2.8 | 57.0 ± 5.9** | 76.0 ± 3.9 | 75.0 ± 4.1 | 67.9 ± 5.0 | 69.2 ± 4.9 |
| hours used/ sleep time | 79.6 ± 5.4 | 75.7 ± 4.1 | 80.6 ± 3.2 | 64.2 ± 6.2* | 73.4 ± 3.1 | 81.4 ± 5.8 | 72.5 ± 5.0 | 72.1 ± 5.2 |

**TABLE 2: Compliance data intensive versus standard support and APAP vs. CPAP**

| | **Intensive support** | | | | **Standard support** | | | |
|---|---|---|---|---|---|---|---|---|
| Time point | DIAG | THER_INI | 3M | 9M | DIAG | THER_INI | 3M | 9M |
| AHI | 43,8 ± 3,6 | 10,2 ± 1,3$^{\#\#}$ | 5,6 ± 0,7$^{\#\#}$ | 3,5 ± 0,8$^{\#\#}$ | 43,6 ± 3,4 | 8,5 ± 0,9$^{\#\#}$ | 6,0 ± 1,0$^{\#\#}$ | 5,9 ± 1,6$^{\#\#}$ |
| ODI | 38,5 ± 4,0 | 4,3 ± 0,7$^{\#\#}$ | 3,1 ± 0,5$^{\#\#}$ | 3,3 ± 0,9$^{\#\#}$ | 38,7 ± 3,5 | 4,1 ± 0,7$^{\#\#}$ | 3,2 ± 0,7$^{\#\#}$ | 4,7 ± 1,2$^{\#\#}$ |
| ArI | 33,9 ± 2,9 | 16,7 ± 1,5$^{\#\#}$ | 14,6 ± 1,4$^{\#\#}$ | 12,3 ± 1,5$^{\#\#}$ | 31,1 ± 3,5 | 14,4 ± 1,8$^{\#\#}$ | 14,2 ± 1,5$^{\#\#}$ | 14,0 ± 1,4$^{\#\#}$ |
| ESS | 10.1 ± 0.6 | | 7.8 ± 0.7 | 6.6 ± 0.7$^{\#\#}$ | 7.4 ± 0.8* | | 5.5 ± 0.6* | 5.8 ± 0.6 |

**TABLE 3: Clinical outcomes intensive versus standard support**

| | APAP | | | | CPAP | | | |
|---|---|---|---|---|---|---|---|---|
| Time Point | DIAG | THER_INI | 3M | 9M | DIAG | THER_INI | 3M | 9M |
| AHI | 41.8±3.5 | 7.4±0.6## | 4.8±0.7## | 3.6±0.8## | 45.5±3.6 | 11.4±1.5## | 6.7±0.9## | 5.4±1.4## |
| ODI | 35.6±3.9 | 3.4±0.7## | 2.1±0.3## | 2.9±0.7## | 41.1±3.8 | 5.0±0.7## | 4.1±0.7## | 4.8±1.3## |
| ArI | 30.6±3.3 | 13.9±1.6## | 12.3±1.3## | 12.9±1.5## | 34.5±3.1 | 17.3±1.6## | 16.4±1.4## | 13.2±1.5## |
| ESS | 8.5±0.8 | | 6.4±0.7 | 5.9±0.7# | 9.3±0.7 | | 7.0±0.7# | 6.6±0.7# |

**TABLE 4: Clinical outcomes APAP vs. CPAP**

| | APAP | | | CPAP | | |
|---|---|---|---|---|---|---|
| Time point | THER_INI | 3M | 9M | THER_INI | 3M | 9M |
| P mean | 8.8 ± 0.3 | 8.2 ± 0.3 | 8.4 ± 0.3 | 9.2 ± 0.2 | 9.4 ± 0.2** | 9.4 ± 0.2** |
| Leakage (95%ile) | 0.27 ± 0.03 | 0.26 ± 0.04 | 0.29 ± 0.03 | 0.28 ± 0.04 | 0.35 ± 0.04 | 0.36 ± 0.04 |

**TABLE 5: Mean pressure and air leakage APAP vs. CPAP**