Long-term Compliance Rates to Continuous Positive Airway Pressure in Obstructive Sleep Apnea*

A Population-Based Study

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Study objectives: To determine long-term compliance rates to continuous positive airway pressure (CPAP) therapy in patients with obstructive sleep apnea enrolled in a comprehensive CPAP program in the community.

Design: Prospective cohort longitudinal study.

Setting: University sleep disorders center.

Patients: Two hundred ninety-six patients with an apnea-hypopnea index (AHI) $\geq$ 20/h on polysomnography.

Interventions: A CPAP device equipped with a monitoring chip was supplied. Within the first week, daily telephone contacts were made. Patients were seen at 2 weeks, 4 weeks, 3 months, and 6 months.

Results: Of the 296 subjects enrolled, 81.1% were males. Mean $\pm$ SD AHI was 64.4 $\pm$ 34.2/h of sleep; age, 51 $\pm$ 11.7 years; and body mass index, 35.2 $\pm$ 7.9 kg/m². The mean duration of CPAP use was 5.7 h/d at 2 weeks, 5.7 h/d at 4 weeks, 5.9 h/d at 3 months, and 5.8 h/d at 6 months. The percentage of patients using CPAP $\geq$ 3.5 h/d was 89.0% at 2 weeks, 86.6% at 4 weeks, 88.6% at 3 months, and 88.5% at 6 months. There was a decrease in the Epworth Sleepiness Scale (ESS) score of 44% by 2 weeks of therapy. The patients continue to improve over the follow-up period, with the lowest mean ESS score observed at 6 months. With multiple regression analysis, three variables were found to be significantly correlated with increased CPAP use: female gender, increasing age, and reduction in ESS score.

Conclusion: A population-based CPAP program consisting of consistent follow-up, "troubleshooting," and regular feedback to both patients and physicians can achieve CPAP compliance rates of > 85% over 6 months.   *(CHEST 2002; 121:430–435)*

Key words: compliance rate; continuous positive airway pressure; obstructive sleep apnea

Abbreviations: AHI = apnea-hypopnea index; CPAP = continuous positive airway pressure; ESS = Epworth Sleepiness Scale; OSA = obstructive sleep apnea; SaO₂ = arterial oxygen saturation; UAH = University of Alberta Hospital

Obstructive sleep apnea (OSA) is a common condition affecting 2% of adult female and 4% of adult male populations,[1] and close to 20% of the elderly population.[2] OSA results in excess daytime sleepiness and decreased health-related quality of life.[3]

Continuous positive airway pressure (CPAP) is an effective therapy for OSA, significantly reducing OSA symptoms in a vast majority of cases.[4] Successful application of CPAP can dramatically improve the health-related quality of life of patients and transform somnolent individuals into energetic and more productive people.[5] Moreover, the use of CPAP can decrease systemic BP and improve cardiovascular performance, thereby decreasing cardiovascular morbidity and mortality associated with OSA.[5]

However, CPAP therapy is often difficult to tolerate and patients frequently stop using it because of discomfort. The nasal mask interface may cause pressure sores, persistent air leakage, claustrophobia,

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nasal congestion, and other side effects that may lead to suboptimal compliance.[6] One study[7] suggests that CPAP compliance might be improved with intensive CPAP support, where these problems can be addressed through a multidisciplinary team approach. However, as these results were produced in a clinical trial setting, it remains uncertain whether high CPAP compliance rates can also be achieved in the community using a similar CPAP program.

Using data from a comprehensive CPAP program implemented in Northern Alberta (population 1.3 million persons) beginning in July of 1999, the aims of this study were to determine: (1) short-term and long-term CPAP compliance rates in the community, (2) baseline predictors for long-term CPAP compliance, and (3) whether CPAP use is associated with sustained improvements in daytime sleepiness in OSA patients with moderate-to-severe disease.

MATERIALS AND METHODS

General Program Description

This study was conducted at the University of Alberta Hospital (UAH) Sleep Disorders Laboratory, in Edmonton, AB, which is the only accredited sleep facility to conduct supervised polysomnography in Northern Alberta. Funding for the CPAP devices were provided by the Alberta Aids to Daily Living, a government agency that oversees the provision of Respiratory Health Services and respiratory equipment to the citizens of Alberta. Funding was also provided for hiring a dedicated CPAP clinic nurse with the specific role of educating and following these patients on a regular basis.

Recruitment and Consent

Between July 1999 and March 2000, all patients undergoing diagnostic polysomnography at the UAH Sleep Disorders Laboratory were considered as potential recruits for this study. All patients were referred for clinical evaluation of possible sleep disorders.

Patients with an AHI ≥ 20/h were considered to be eligible candidates to receive a CPAP device provided by Alberta Aids to Daily Living without any cost to the patient. Some subjects with an AHI < 20/h also received CPAP therapy if there were significant clinical indications for CPAP therapy. All patients receiving CPAP devices were asked to sign a consent form indicating their willingness to comply with CPAP therapy, and their explicit understanding that the CPAP device must be returned if their compliance was deemed unsatisfactory, as measured through a pressure-sensing chip included in each CPAP unit.

Polysomnography

The diagnostic polysomnographic studies were performed at the UAH Sleep Disorders Laboratory. Recordings were performed overnight with continuous monitoring of EEG, electro-oculogram, chin electromyogram, oronasal airflow (by thermistor), chest and abdominal respiratory movements, oximetry, anterior tibialis electromyogram, body position sensor, and snor-

ing noise sensor. Digitized signals were stored on optical disk and analyzed using software (Sandman Elite Version 5.0; Nellcor Puritan Bennett [Melville] Ltd., Ottawa, ON, Canada). Manual scoring was done by trained, certified technologist to verify the automated scoring system in every case. All sleep recordings were verified by American Board of Sleep Medicine-certified sleep specialists who provided descriptive diagnostic interpretation of the polysomnographic studies.

Scoring of sleep staging was done using published criteria.[8] An apnea episode was defined as a cessation of oronasal airflow for > 10 s. An hypopnea episode was defined as a diminution of the amplitude of respiratory signals by > 50% for > 10 s, with or without desaturation. An obstructive respiratory event was scored when there was evidence of paradoxical chest and abdomen movement. A central respiratory event was scored when both the chest and abdominal respiratory movements were diminished.

Follow-up Protocol

All CPAP subjects underwent an educational session prior to commencement of CPAP therapy, which included a 26-min video presentation (produced locally by the Sleep Apnea Society of Alberta) and a one-on-one discussion session with a qualified CPAP clinic nurse. The videotape presented information on OSA, including symptoms, health consequences, and pathophysiology, and a detailed explanation on the use of the CPAP device. The key concepts from this videotape was subsequently reinforced by a CPAP nurse who had prior training and experience in polysomnographic studies and in basic respiratory therapy principles relevant to the care of the CPAP devices. Reading materials were given to each subject, with a pamphlet on OSA, CPAP devices, suggestions for troubleshooting and remedies, as well as a follow-up schedule.

Subjects were instructed to contact the CPAP clinic nurse daily by telephone within the first week. Subsequently, the subjects were seen at 2 weeks, 4 weeks, 3 months, and 6 months after starting CPAP therapy. At each visit, the compliance data were downloaded from the CPAP device and reviewed by the CPAP clinic nurse together with the subjects. Any concerns or questions were addressed immediately by the CPAP clinic nurse, and changes in the CPAP setting, nose/face mask, or circuit were made after consultation with the responsible sleep physician if necessary. If nasal complaints were significant, either topical steroid spray or anticholinergic nasal spray was prescribed. If these failed, a heated humidifier was then made available. During the study period, only 15 patients required a heated humidifier. Each follow-up visit lasted 15 to 30 min.

The compliance data from each visit were tabulated and reported to the referring sleep physician. If there were doubts about a patient's compliance or willingness to continue with the program, the referring physician made personal contacts with the patient by telephone or through direct in-person interviews to resolve barriers to adequate compliance. Through a collaborative team effort, patient problems were addressed and resolved.

CPAP Device

The CPAP device used was the Aria LX model (Respironics; Pittsburgh, PA). There were various nose masks, face masks, nasal pillows, and head-harnesses used, depending on individual facial structure and preference. Passive humidifiers were routinely used. Heated humidifiers were used when necessary. In all CPAP devices, there was a built-in monitoring chip for collection and storage of CPAP usage data. The monitoring chip only registers use when the set pressure was maintained, not just when the CPAP device was turned on. The monitoring device provided

time of days used, hours of daily use, and days used per month. From these data, we calculated:

Percentage of days CPAP was used

$$= \frac{\text{No. of days when} \geq 1 \text{ h of use was recorded}}{\text{total No. of follow-up days}}$$

Mean daily use (hours)

$$= \frac{\text{total hours of CPAP used}}{\text{total No. of follow-up days}}$$

Mean daily use on days CPAP was used

$$= \frac{\text{total hours of CPAP used}}{\text{total No. of days when} > 1 \text{ h of use was recorded during follow-up}}$$

Measurements

At the start of the CPAP program, and during each follow-up visit, subjects were asked to complete a questionnaire regarding the degree of daytime sleepiness (the Epworth Sleepiness Scale [ESS]).[9]

Statistical Analysis

The means and SDs of continuous variables were compared using Student's two-tailed t test. Nonnormally distributed variables were compared using the Wilcoxon rank-sum test. Ordinal and binary variables were compared using a χ^2 test. A trend test was used to determine significance of temporal relationships in the use of CPAP over the 6 months of follow-up. To determine important predictors of 6-month compliance to CPAP, we used a multiple logistic regression model. We employed a step-wise regression model to select out significant variables; only those variables that produced a p value < 0.05 were included in the final model. Odds ratios are presented with 95% confidence intervals, and reported p values are two-tailed. All p values < 0.05 were considered statistically significant. All analyses were performed with statistical software (SAS release 8.1; SAS Institute; Cary, NC).

RESULTS

Study Cohort

During the study period, 1,007 patients underwent diagnostic polysomnography for a suspected sleep disorder. Of these, 296 patients (29.4%) had an AHI $\geq$ 20/h and were invited to join the CPAP program. No patients refused, and all were followed up for the duration of the study period. We did not lose any patients during follow-up. The baseline demographic and sleep study features for patients with and without OSA are shown in Table 1. Patients with OSA were slightly older, more obese, and more likely to be men than those without OSA. Moreover, OSA patients displayed increased fragmentation of sleep as evidenced by lower sleep efficiency and increased representation of stages 1 and 2 sleep than those without OSA. As expected, OSA patients had a higher AHI and lower mean arterial oxygen saturation (SaO$_2$) compared to those without OSA.

Table 1—Baseline Demographics and Sleep Characteristics of Patients With and Without OSA*

Variables	No OSA	OSA	p Value
Patients, No.	711	296	0.001
Age, yr	47.1 ± 13.0	51.0 ± 11.7	0.001
Male patients, %	59.6	81.1	0.001
Body mass index, kg/m^2	30.4 ± 7.1	35.2 ± 7.9	0.001
Total sleep time, min	185.1 ± 166.2	101.0 ± 117.5	0.001
Sleep efficiency, %	77.2 ± 15.9	71.6 ± 13.7	0.001
Sleep onset latency, min	20.3 ± 23.9	17.9 ± 19.1	0.077
Stage 1, %	8.9 ± 3.7	18.9 ± 15.1	0.001
Stage 2, %	45.2 ± 11.3	51.8 ± 18.0	0.001
Stage 3, %	7.4 ± 3.7	7.3 ± 7.1	0.874
Stage 4, %	20.9 ± 10.0	13.1 ± 14.0	0.001
Rapid eye movement sleep, %	16.3 ± 8.4	8.9 ± 9.2	0.001
Obstructive apnea index†	0.5 ± 1.2	17.5 ± 23.3	0.001
Obstructive AHI†	5.8 ± 4.9	64.4 ± 34.2	0.001
SaO$_2$, %	94.0 ± 27.8	90.7 ± 3.5	0.022
Periodic leg movement index†	10.5 ± 18.9	9.6 ± 19.8	0.479

*Data are presented as mean ± SD unless otherwise indicated.
†No. of events per hour of sleep.

Compliance to CPAP Therapy for OSA Patients

The average CPAP setting at initiation was 11.6 ± 2.7 cm H$_2$O (mean ± SD). The use of CPAP over the first 6 months of therapy is shown in Table 2. The average hours of CPAP use during the study period was well maintained; however, there was a slight decline in the total percentage of days that CPAP was used over the first 6 months of therapy.

Because there is no universally accepted definition of CPAP compliance, CPAP compliance was defined in multiple ways in Table 3 using mean hours of daily CPAP use. Even using a very stringent definition of CPAP compliance (ie, $\geq$ 4.5 h/d), 83% and 79% of the patients in this program were compliant with their CPAP therapy at 3 months and 6 months, respectively.

ESS

ESS scores at baseline and during the follow-up period are plotted in Figure 1. By 2 weeks of therapy, there was a dramatic decrease in the subjective feeling of sleepiness as measured by the ESS (44% relative reduction). The ESS scores at baseline, 2 weeks, 4 weeks, 3 months, and 6 months of therapy were 14.1 ± 5.6, 7.9 ± 5.3, 7.1 ± 4.7, 6.0 ± 4.5, and 5.5 ± 4.4, respectively. The test for trend (toward decreasing ESS scores with increased follow-up time) was significant (p = 0.001), suggesting an inverse monotonic relationship between elapsed time since the start of CPAP therapy (up to 6 months) and daytime sleepiness.

Table 2—CPAP Utilization Data Over 6 Months of Follow-up*

Variables	2 wk	4 wk	3 mo	6 mo
Days that CPAP was used, %	95.2	92.9	90.5	85.4
Mean daily use, h†	5.7 ± 1.8	5.7 ± 1.9	5.9 ± 1.9	5.8 ± 2.1
Mean daily use on days CPAP was used, h‡	5.8 ± 1.7	6.0 ± 1.7	6.2 ± 1.8	5.9 ± 2.2

*Data are presented as mean ± SD unless otherwise indicated. None of the relationships were significant at the $p < 0.05$ level.

†This value was calculated by dividing the total hours of CPAP used by the number of days during follow-up including days on which CPAP was not used.

‡This value was calculated by dividing the total hours of CPAP used by the number of days CPAP was used (*ie*, days on which CPAP was not used was excluded).

Predictors of CPAP Use

Using a step-wise approach, we determined the important clinical predictors of CPAP use at 6 months after CPAP initiation. In our initial model, we included changes in ESS score at 6 months compared to baseline, total sleep time, sleep efficiency, AHI, mean SaO_2 during sleep, gender, age, body mass index, periodic leg movement index, and various sleep stages, and correlated these variables to the mean hours of daily use of CPAP. In our final multiple regression model, only three variables were found to be significantly correlated with CPAP use: change in ESS scores ($p = 0.003$), gender ($p = 0.020$), and age ($p = 0.021$). There was a negative association between the magnitude of ESS score change and CPAP use, such that a 10-U decrease in ESS score was associated with a 0.76 ± 0.11-h increase in the amount of CPAP used per day of follow-up. Age, however, was positively associated with CPAP use; a 10-year increment in age was associated with 0.24 ± 0.11-h increase in CPAP use (Fig 2). Women, on average, used CPAP more frequently than men by 0.76 ± 0.32 h.

DISCUSSION

This population-based CPAP program produced several interesting findings. First, we observed that > 92% of OSA patients in this program used CPAP for > 2.5 h/night on average for the first 6 months of the program. Even using a more stringent criterion for compliance (*ie*, ≥ 4 h of CPAP use per night), 84% of the eligible CPAP recipients were compliant with CPAP over the first 6 months of the program. Second, as expected, with the application of and compliance with CPAP therapy, there was a marked improvement in the patients' daytime sleepiness as measured by the ESS. In just 2 weeks following initiation of CPAP therapy, we observed a 44% relative reduction in the average daytime sleepiness for our cohort of patients. More importantly, this improvement was sustained for the duration of the 6-month follow-up period, suggesting that continued compliance with CPAP provides long-term benefits for patients with OSA. Third, women, older patients, and those who experienced marked improvements in their daytime sleepiness were more likely to be compliant with CPAP at 6 months than those without these parameters.

Several large studies[10–13] have been previously published concerning CPAP compliance in the community, which have shown compliance rates ranging from 65 to 80%. Such a wide variation in the reported compliance rates may in part be related to the way in which compliance has been measured. For instance, McArdle and coworkers[14] reported a 6-month compliance rate of 85% using a program similar to ours. However, their definition of compliance was > 2 h/night of CPAP use.[14] Moreover, they used built-in counters on CPAP devices to capture utilization data; however, these devices tend to overestimate actual compliance as measured by pressure-actuated devices such as the one we used.[15,16] In an earlier work, Kribbs and coworkers[15] used a microprocessor to measure "actual" compliance and reported an average duration of CPAP use of 4.9 ± 2.0 h (on days that CPAP was used) over a 3-month period. In our program, we observed an average duration of CPAP use of 6.2 ± 1.8 h over a similar time frame. In a more recent study, Pepin and coworkers[16] reported a 3-month compliance rate of 74% using criteria of > 4 h of use per day. Even using very stringent criteria for compliance in our

Table 3—Percentage of Total Patients With OSA Who Complied With CPAP Therapy According to Different Definitions of Compliance*

Mean Daily Use, h	2 wk	4 wk	3 mo	6 mo
≥ 2.5	93.9	93.5	94.1	92.3
≥ 3.0	91.4	91.4	92.1	91.5
≥ 3.5	89.0	86.6	88.6	88.5
≥ 4.0	83.2	80.9	87.1	83.8
≥ 4.5	78.3	75.6	83.1	78.5

*Data are presented as %. None of the relationships were significant at the $p < 0.05$ level.
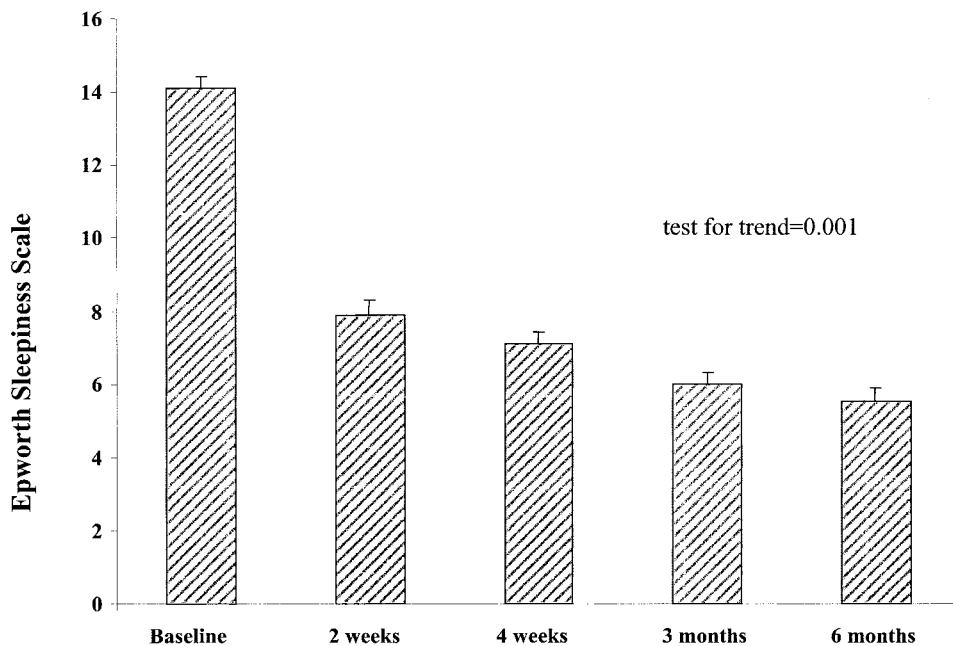
FIGURE 1. Mean ESS scores at baseline and during follow-up at 2 weeks, 4 weeks, 3 months, and 6 months. Error bars represent SEM.

study ($\geq$ 4 h of use), we found that 87% and 84% of patients were compliant at 3 months and 6 months, respectively, suggesting our program was effective in securing adequate compliance in most OSA patients.

We believe that several factors were important in producing good CPAP compliance among our cohort of patients. First, we carefully selected patients with "objective" documentation of OSA (using an AHI of $\geq$ 20/h) for our program and systematically treated all of them with CPAP. Patients with an AHI < 20/h were enrolled on a case-by-case basis (data not included in this analysis). Second, we designed our program to maximize the compliance rate in our participants. We incorporated the elements that have been suggested by previous investigators[6] to be important for improving CPAP compliance over the long term. These measures included intense patient education, use of a dedicated CPAP nurse to ensure
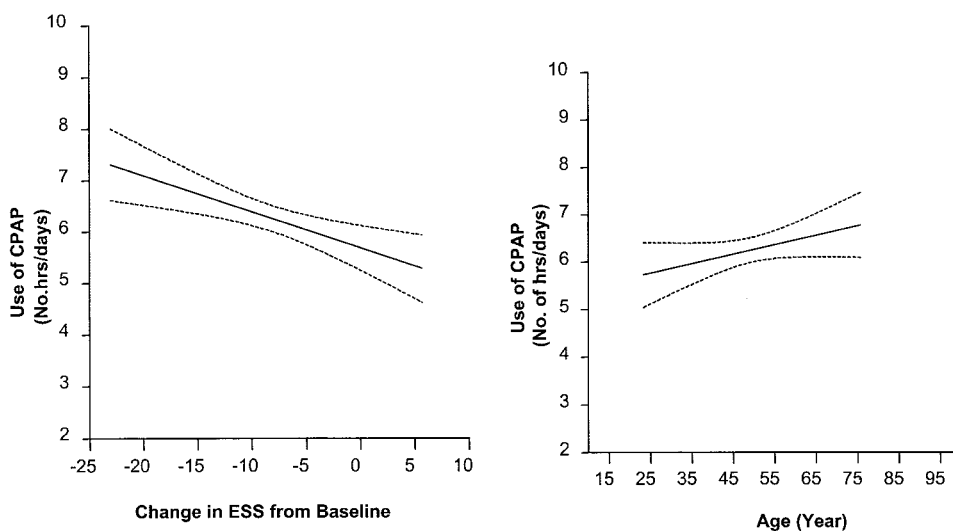

FIGURE 2. *Left panel*: Relationship between the use of CPAP (No. of hours per day) and change in actual ESS score from baseline to 6 months. *Right panel*: Relationship between the use of CPAP (No. of hours per day) and age. Dotted lines represent 95% confidence limits.

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close follow-up of patients (particularly during the first 2 weeks of therapy), troubleshooting when necessary, and rapid involvement of sleep physicians to solve compliance issues for difficult-to-manage patients. Third, we provided the CPAP device and ancillary services free of charge to the patients, removing significant financial concerns for patients.

Our findings that increasing age, female sex, and changes in ESS scores from baseline were associated with CPAP compliance are consistent with findings by McArdle and coworkers[14] but dissimilar to those from Janson and coworkers.[17] However, the latter study employed a case-control design (which is prone to more biases),[18] had smaller study sample, and, most importantly, used only oximetric results for OSA diagnosis, which may have led to a diagnostic misclassification.

The present study has certain limitations. First, while good CPAP compliance was achieved in a vast majority of OSA patients in our program, due to the nature of the study design, it remains uncertain which elements or components of the program were responsible for this success. Indeed, the uncontrolled protocol used in this study makes it difficult to attribute the excellent CPAP compliance rates directly to the comprehensive CPAP program. Nevertheless, the totality of evidence from our study, as well as those of others,[7,15] suggests that high compliance rates to CPAP can be achieved in a environment that fosters patient education, comprehensive follow-up, and integrated care. Second, before we started the program, we decided collectively to use the criteria of an AHI $\geq$ 20/h as the treatment threshold. This decision is partly based on previous report of increased mortality in OSA subjects with an AHI $\geq$ 20/h who are untreated.[19] There is evidence that some patients with an AHI < 20/h may also benefit symptomatically from nasal CPAP, but the results are not definitive and it is not possible at the moment to clearly identify the subjects (with an AHI < 20/h) who might benefit. We do not wish to imply that OSA patients with an AHI < 20/h should not be treated. Our study did not include these subjects, and therefore we cannot report on the CPAP compliance rate in these subjects. Further studies will be necessary to determine the treatment threshold and compliance rate in OSA subjects with mild disease.

In summary, our study findings suggest that high CPAP compliance rates are achievable in the community through a comprehensive CPAP program that provided free CPAP devices, extensive education, and follow-up services for symptomatic OSA patients with moderate-to-severe disease through a multidisciplinary team approach. Future studies are needed to determine which of the components of the program are the critical pieces in effecting excellent long-term CPAP compliance rates in the community.

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