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take medication. Why quite a few of the patients who do not believe in the efficacy of drugs nevertheless take drugs remains to be investigated. Long latency to sleep onset, frequent awakenings, frequent dreams, increased time in bed, and somewhat decreased total sleep time are main characteristics of 'poor sleep'. Its incidence varies markedly between diagnostic groups.

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Sleep Behavior of Senile-Arteriosclerotic Patients

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In order to control the success of drug treatment in severely sleepdisturbed senile-arteriosclerotic patients, EEG studies are of great value. However, due to obvious reasons, such studies can be carried out only

with a small number of patients and during a limited number of nights. As we have shown in recent studies, systematic observation during 3 months of sleep behavior of such patients reveals some insight into their sleep disturbance and makes possible a quantitative comparison of the effects of different drugs, and placebo [Heimann, 1970], For such studies the nursing hospital personnel are instructed to observe the patients every hour; the opening and closing of the door and the light of a flash light are considered as standard stimuli. The personnel establish during each round whether the patient is asleep without moving (3 points), whether he reacts to the stimulation by moving and/or waking up (2 points), or whether he is already awake (1 point). The hourly observations are entered in a sleep chart. In the morning the personnel have to rate whether, on awakening, the patient is fresh (score 1), tired (score 2) or drowsy (score 3). In our previous study [Heimann, 1970] we have compared two groups of senile-arteriosclerotic patients: one, with severe sleep disturbance necessitating the use of hypnotics, which was kept for 1 month under placebo, and a second control group without severe sleep disturbance and without placebo. As can be seen from the following table, the severely sleepdisturbed group under placebo slept longer than the control group. Furthermore, the severely sleep-disturbed patients assumed a kind of an 'all-or-none principle', in that during the month under placebo, there were nights with sleep scores as high as those observed during the months with drugs, or there were nights when the patients did not fall asleep at all and had to be given medication some hours later. In a second study lasting 3 months we examined the sleep behavior of 30 senile-arteriosclerotic patients with severe sleep disorders under

Table I. Average sleep scores

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Fig. 1. Sleep profile of a patient of subgroup B, many nights with additional medication.

10 mg nitrazepam, 20 mg HUF 2333 (methyl-piperazin-dibenzoazepin)1 and placebo. The same scoring method as in our first study was used. According to the personnel all these patients needed a hypnotic every night. The patients were rated every hour between 20.00 and 06.00 h. Drugs and placebo were systematically permuted and distributed to the 30 patients in a randomized fashion.

The sum of points for one night, i.e. the nightly sleep scores were plotted for each patient over the period of observation to obtain his sleep profile. 17 of 30 patients completed the study.

Figure 1 shows the sleep profile of a patient under placebo and drugs, respectively. The nights with the minimal sleep scores correspond to the nights when the patient did not fall asleep and when he was given an additional medication some hours later. These nights occurred significantly more often during placebo treatment than during the month under 10 mg Mogadon (p < 0.05); the difference between placebo and HUF 2333, however, was not significant. As in our earlier study, there were nights during the month under placebo with sleep scores as high as those during the month under active drugs. Again, this suggests the 'all-or-none' principle of sleep disturbance in a larger group of patients.

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Fig. 2. Sleep profile of a patient of subgroup A, few nights with additional medication.

Concerning the need for additional medication, the group of 17 patients can be separated into two distinct subgroups: Subgroup A, consisting of 9 patients who rarely needed additional medication (a total of 10 during 3 months), and subgroup B with 8 patients who often needed an additional medication (total of 46).

The patient whose sleep profile is shown in figure 1 belongs to subgroup B. Figure 2 shows a sleep profile of a patient of subgroup A, i.e. a subject who rarely received the additional medication. During the month under placebo, this patient presents an irregular sleep behavior with nights of low, medium and high sleep scores. In subgroup A, therefore, the 'all-or-none' principle is less pronounced. If one compares the deep sleep score (3 points) of both subgroups under placebo, there are no significant differences. Therefore, there is no indication that the sleep disturbance in subgroup A is any lighter than that in subgroup B; the difference in the sleep disturbance is not quantitative but rather qualitative in nature. The application of the additional medication is a consequence, in general, of a verbal or psychomotor agitation of the patient. The sleep chart typically contains the following remarks when additional medication was given: 'gets up constantly', 'cries without interruption 'walks around incessantly

Another interesting difference between subgroups A and B concerns

the effect of HUF 2333 which in a dose of 20 mg affects the patients of subgroup A only, i.e. the patients without agitation. However, 10 mg of Mogadon shows an influence in both groups.

As to the condition of the patients after awakening the following observations were made. If the nights with an additional medication are eliminated, the condition of the patients in both subgroups was best during the month of placebo, both groups show about the same score. 20 mg of HUF 2333, which influenced only the sleep disturbance without agitation, led to a significant decrease of vigilance in the morning after awakening in this group. In subgroup B, which was characterized by agitation and in which this drug did not have an overt effect, there was no significant decrease of vigilance in the morning after awakening.

Nitrazepam, which was equally effective in both subgroups, caused

Nitrazepam, which was equally effective in both subgroups, caused pronounced tiredness and drowsiness in the morning in subgroup B and even more so in the group of sleep disturbance without agitation, i.e. subgroup A.

Summary

According to our earlier studies, the patients with severe sleep disturbance slept longer under placebo than patients without severe sleep disturbance of the same diagnostic group. On particular nights these patients had sleep scores which are not lower than those during drug periods. For the time being, we cannot explain this 'all-or-none' principle. There seems to be no periodicity, no systematic distribution; furthermore, we note that in those instances when the application of a sleep-inducing compound favorably influenced the sleep behavior, the improvement had to be paid for by a loss of vigilance on awakening in the morning.

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