Validation of the Idiopathic Hypersomnia Severity Scale in the Czech Republic

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Abstract: We have verified the eligibility of the Idiopathic Hypersomnia Severity Scale (IHSS) as a basic clinical tool for determining the subjective severity of illness in patients with idiopathic hypersomnia (IH) in the Czech Republic. Total of 37 patients with a diagnosis of IH (9 men, 28 women, mean age 40.2 ± 12.8) completed the IHSS scale. At the same time, they were instructed to complete the Epworth Sleepiness Scale (ESS), the Fatigue Severity Scale (FSS), the Hospital Anxiety and Depression Scales (HADS-A and HADS-D), and a short version of the Quality of Life Questionnaire (SF-36). The control group consisted of 88 age- and sex-matched healthy volunteers. The IHSS scale showed good internal consistency of the questionnaire using Cronbach's α, which was 0.88. The KMO (Keiser-Meyer-Olkin index) was 0.72, confirming sufficient structural validity of the questionnaire. The correlation of the total IHSS score with the ESS ($\rho = 0.59$, $p=0.0001$) and FSS ($\rho = 0.84$, $p<0.0001$) as well as with the HADS-A scales ($\rho = 0.64$, $p<0.0001$), HADS-D ($\rho = 0.79$, $p<0.0001$) and SF-36 in both the mental ($\rho = –0.85$, $p<0.0001$) and physical health ($\rho = –0.66$, $p<0.0001$) components. The IHSS is a convenient and easy-to-apply clinical tool to assess subjective severity of illness, which describes well the symptoms of idiopathic hypersomnia and assesses their impact on health and daily activities.

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Introduction

Idiopathic hypersomnia (IH) was firstly described by Czech neurologist, assistant professor doctor Bedrich Roth (Roth, 1976). The disease can be characterized by a high need for sleep during the day with longer, unrefreshing naps, prolonged night-time sleep and difficult, prolonged awakening, the so-called sleep inertia (American Association of Sleep Medicine, 2014). It is a rather rare neurological disorder, the clinical symptoms of which partially overlap with narcolepsy (Billiard and Sonka, 2016). Narcolepsy is however much less frequent, sources mention between 3–10 times less frequent than IH (Nevšímalová and Šonka, 2020; Leschziner, 2022). Even though hypersomnolence is the main and the most debilitating symptom, patients often report other non-specific symptoms, such as physical and mental fatigue, autonomic symptoms, memory disturbances and loss of concentration (Anderson et al., 2007; Vernet and Arnulf, 2009; Buskova et al., 2022). IH often manifests along with other comorbidities, which can interfere with the classification of sleepiness and thus assessment of severity of IH (Buskova et al., 2022). Medical condition of patients suffering from IH leads to decrease in quality of life; their social interactions and work activities are disturbed and there is also an increased risk of car accidents (Ozaki et al., 2008; Dauvilliers et al., 2009; Pizza et al., 2015). Pathophysiology of IH has not been clarified yet, no specific biomarkers have been identified (Billiard and Sonka, 2022), which further complicates the diagnostic procedure. Treatment options include mainly off-label prescribed psychoactive drugs and wakefulness-enhancing medication, which are approved for narcolepsy treatment (Evangelista et al., 2018).

In clinical practice, a simple screening tool is therefore needed to assess the frequency/severity of individual symptoms and their overall impact on daily activities, and which would also be suitable for evaluating the effect of treatment. Until today, the most widely used scale has been Epworth Sleepiness Scale (ESS) (Johns, 1991), which, however, does not address all the basic symptoms of IH, such as prolonged night-time sleep and sleep inertia. The whole spectrum of symptoms cannot be addressed neither by Hypersomnia Severity index (IHS), which was originally created to assess the severity of sleepiness in psychiatric disorders (Kaplan et al., 2019), nor Sleep Inertia Questionnaire (Kanady and Harvey, 2015). In 2019, the French colleagues presented Idiopathic Hypersomnia Severity Scale (IHSS) (Dauvilliers et al., 2019), which best meets the requirements for a balanced description/quantification of all clinical signs of IH. Our aim was to verify its psychometric properties in a cohort of patients with IH in the Czech Republic and to determine whether it fully reflects the difficulties for which patients come with respect to their daily activities.

Material and Methods

Participants

The cohort consisted of 37 adult patients with idiopathic hypersomnia from 2 sleep centres (27 patients from the Centre for Sleep and Wakefulness Disorders of the First Faculty of Medicine of Charles University and General University Hospital in Prague, 10 patients from the Department of Sleep Medicine of the National Institute of Mental Health, Klecany and the Third Faculty of Medicine of Charles University). These patients were either invited to the sleep laboratory to undergo diagnostic procedure between 6/2020 – 9/2022 due to suspicion of idiopathic hypersomnia or were already diagnosed with IH and were invited for regular visit as part of their clinical follow-up. In all the patients, the diagnosis was made on the basis of currently valid ICSD-3 (International Classification of Sleep Disorders, 3rd Edition) criteria: irresistible need for sleep during the day and falling asleep > 3 months, cataplexy is not present, mean sleep latency at MSLT (multiple sleep latency test) ≤ 8 min with a finding of < 2 periods of REM (rapid eye movement) sleep (occurrence of REM sleep in the first 15 minutes after falling asleep during the night can replace 1 period of REM sleep during MSLT), the total sleep time in 24 hours is ≥ 660 min during polysomnographic monitoring or actigraphic recording associated with a sleep diary after averaging from a period of at least 7 days when sleep was not restricted. The insufficient sleep syndrome and/or hypersomnia associated with another disease needs to be excluded (American Association of Sleep Medicine, 2014). In patients diagnosed before 2014, when the current ICSD-3 classification was introduced, it was verified that the clinical picture at the time of diagnosis was fully consistent with the ICSD-3 diagnostic criteria.

The control group consisted of 88 healthy volunteers who participated in follow-up sleep studies as control subjects. 52 of them had polysomnography performed in the previous year, which showed no sleep disorder. No one in the control group was followed for any disease that may be manifested by sleep disorders. They were not taking any medication that affected sleep or daytime alertness.

The implementation of this study was part of the grant project Gut Microbiome and Autoimmune Mechanisms in Patients with Central Hypersomnia, which was approved by the Ethics Committees of both departments. All patients signed an informed consent form to participate in the study.

Data collection

The English version of the IHSS was provided to the researchers for the purposes of the study by the MAPI Research Institute, Lyon, France (No. 218774). First, a double reverse translation of the IHSS from English to Czech was performed by a bilingual native speaker and sleep medicine specialists from both centres (JB, KŠ, SN). The translation was merged and discussed until a consensus was reached. Subsequently,

5 patients were asked to comment on whether the questions were clear and comprehensible, which they confirmed.

The Idiopathic Hypersomnia Severity Scale consists of 14 questions that measure the severity, frequency, and impact on daily activities of the 3 key symptoms of idiopathic hypersomnia. All the questions relate to the last month of the disease. A total of 5 questions are about night-time sleep and sleep inertia, 4 questions are focused on daytime sleep and the associated sleep inertia, and 5 questions are about the impact of the disease on daytime functioning due to excessive daytime sleepiness. The scale also includes 2 questions (No. 1 and 2) about the duration and quality of night-time sleep, 3 questions (No. 3, 4 and 5) about sleep inertia when getting up in the morning and 1 question (No. 8) when waking up from daytime sleep, another 3 questions (No. 6, 7 and 9) are focused on daytime symptoms (occurrence of daytime naps, daytime sleepiness). Questions 10–14 relate to the effects of daytime activities and functioning due to sleepiness. Frequency, intensity, and consequences are evaluated using a 3- or 4-point Likert scale. The total score represents the sum of the points of all questions, ranging between 0–50 points, higher scores indicate greater disease severity.

In the preparation of this study, the authors evaluated as irrelevant question No. 14: "Do you consider that your hypersomnolence is a problem in terms of your driving a car?", because in the Czech Republic, insufficiently compensated idiopathic hypersomnia is not compatible with driving motor vehicles. Patients without a driver's license, as well as those who do not experience this limitation, answered in the same way: "No problem/I do not drive at all for other reasons" (= 0 points), which may distort information regarding the actual impact of daytime sleepiness on driving motor vehicles. The questionnaire was presented to patients during a diagnostic stay in a sleep laboratory or during an outpatient visit as part of long-term follow-up. No patient completed the questionnaire repeatedly. The native language of all the respondents was Czech.

In addition to the IHSS, patients completed other questionnaires: ESS (Johns, 1991), Fatigue Severity Scale (FSS) (Hjollund et al., 2007), Short Form Health Survey-36 (SF-36) (Ware and Gandek, 1998) and Hospital Anxiety and Depression Scale (anxiety subscale HADS-A and depression subscale HADS-D) (Zigmond and Snaith, 1983).

Statistical analysis

To compare the total values of the IHSS questionnaire, the individual questions of the IHSS questionnaire and clinical and demographic characteristics between selected groups of patients, the non-parametric Mann-Whitney U-test was used; in the case of categorical variables the Fisher exact test was performed. To express the correlations of quantities, the nonparametric Spearman correlation coefficient was used. The consistency of the IHSS questionnaire was evaluated by the Cronbach α coefficient and the Keiser-Meyer-Olkin (KMO) index. ROC (receiver operating

characteristic) analysis was used to set thresholds/cut-offs for discrimination between untreated patients and healthy controls. The optimal threshold was searched using the Youden method. A linear model was used to compare the total values of the IHSS questionnaire between patients and controls, taking into an account the influence of selected variables. The P-values were adjusted to multiple comparisons using the Holm method. The analysis was processed in statistical software R, version 4.2.1.

Results

Demographic parameters and descriptive data

The study included 37 patients diagnosed with IH (9 men, 28 women, mean age 40.2 ± 12.8 years, range 18–66 years), BMI (body mass index) 22.2 ± 4.7. The mean age at onset was 23.4 ± 13.4 years, the average duration of the disease was 16.8 ± 13.4 years. Of the total number of participants, 16 patients were currently being treated. Of these patients, 12 patients were treated with modafinil, 4 patients

Table 1 – Mean total IHSS score (± standard deviation) for all patients and for treated/untreated patients with idiopathic hypersomnia. There was no significant difference between treated and untreated patients on any question (p<0.05)

Idiopathic Hypersomnia Severity Scale		N=37	Treated (N=16)	Untreated (N=21)	p<0.05
1	What for you is the ideal duration of night-time sleep (at the weekend or on holiday, for example)?	1.95 ± 0.81	1.88 ± 0.96	2.00 ± 0.71	NS
2	When circumstances require that you get up at a particular time in the morning (for example for work or studies, or to take the children to school during the week), do you feel that you have not had enough sleep?	2.22 ± 0.85	2.13 ± 1.02	2.29 ± 0.72	NS
3	Is it extremely difficult for you, or even impossible, to wake in the morning without several alarm calls or the help of someone close?	1.92 ± 1.09	1.69 ± 1.14	2.10 ± 1.04	NS
4	After a night's sleep, how long does it take you to feel you are functioning properly after you get up (in other words fully functional, both physically and intellectually)?	2.46 ± 1.41	2.25 ± 1.44	2.62 ± 1.40	NS

Idiopathic Hypersomnia Severity Scale		N=37	Treated (N=16)	Untreated (N=21)	p<0.05
5	In the minutes after waking up, do you ever do irrational things and/or say irrational things, and/or are you very clumsy (for example, tripping up, breaking things or dropping things)?	1.05 ± 1.08	1.06 ± 1.12	1.05 ± 1.07	NS
6	During the day, when circumstances allow, do you ever take a nap?	2.27 ± 1.10	2.31 ± 1.20	2.24 ± 1.04	NS
7	What for you is the ideal length of your naps (at the weekend or on holiday, for example)?	2.00 ± 0.88	1.94 ± 0.93	2.05 ± 0.86	NS
8	In general, how do you feel after a nap?	1.49 ± 0.77	1.56 ± 0.63	1.43 ± 0.87	NS
9	During the day, while carrying out activities that are not very stimulating, do you ever struggle to stay awake?	2.57 ± 1.17	2.63 ± 1.20	2.52 ± 1.17	NS
10	Do you consider that your hypersomnolence has an impact on your general health (i.e. lack of energy, no motivation to do things, physical fatigue on exertion, decrease in physical fitness)?	2.41 ± 1.36	2.56 ± 1.26	2.29 ± 1.45	NS
11	Do you consider that your hypersomnolence is a problem in terms of your proper intellectual functioning (i.e. problems with concentration, memory problems, decrease in your intellectual performance)?	2.11 ± 1.43	2.06 ± 1.39	2.14 ± 1.49	NS
12	Do you consider that your hypersomnolence affects your mood (for example sadness, anxiety, hypersensitivity, irritability)?	2.05 ± 1.13	2.19 ± 1.11	1.95 ± 1.16	NS
13	Do you consider that your hypersomnolence prevents you from carrying out daily tasks properly (family-related or household tasks, school, leisure or job-related tasks)?	2.03 ± 1.38	2.25 ± 1.34	1.86 ± 1.42	NS
14	Do you consider that your hypersomnolence is a problem in terms of your driving a car?	0.49 ± 0.90	0.56 ± 0.89	0.43 ± 0.93	NS

IHSS – Idiopathic Hypersomnia Severity Scale; NS – not significant

were taking methylphenydate, 4 patients were currently receiving SSRIs (escitalopram, citalopram, fluoxetine, sertraline), 1 patient was taking pregabalin.

The mean IHSS score for the study cohort of patients with IH was 26.97 ± 9.89 points (range 9–44 points). The mean scores for each question ± SD (standard deviation) for all patients and separately for those who were treated (N=16) and untreated (N=21) are shown in Table 1. Treated patients did not differ significantly from untreated patients in terms of age, gender, BMI, age at onset or duration. The average ESS score was 14.5 ± 3.6 points (range 9–22 points), mean FSS score 44.8 ± 14.4 points (range 9–63), HADS-A: 8.4 ± 4.8 (0–19), HADS-D: 7.7 ± 5.4 (0–19), SF-16 physical health: 67.2 ± 18.7% (24–96%), SF-36 mental health: 48.6 ± 21.1% (9–86%).

The control group included 88 healthy subjects (42 men, 46 women, mean age 38.8 ± 10.3 years, range 18–64 years), BMI 23.2 ± 3.6. The average IHSS score was 6.6 ± 3.1 points (range 2–13 points). The control group's IHSS score was significantly lower than the patient's score even after accounting for the effect of age, gender, BMI, and ESS ($p<0.0001$).

Psychometric properties of the questionnaire

The internal consistency of the questionnaire (reliability) was confirmed using the Cronbach α coefficient, which is 0.88 for the entire cohort of patients with IH, 0.88 for the group of treated patients and 0.89 for the group of untreated patients. The KMO index for the whole cohort is 0.72, which confirms sufficient structural validity of the questionnaire.

In terms of convergent validity, we noted a correlation between IHSS and ESS ($\rho = 0.59$, $p=0.0001$, Figure 1) and FSS ($\rho = 0.84$, $p<0.0001$, Figure 2) as well as with the HADS-A scales ($\rho = 0.64$, $p<0.0001$, Figure 3), HADS-D ($\rho = 0.79$, $p<0.0001$, Figure 4), SF-36 in the mental subscale ($\rho = –0.85$, $p<0.0001$, Figure 5) and physical health subscale ($\rho = –0.85$, $p<0.0001$, Figure 6).

We did not identify a significant difference in total IHSS score between treated and untreated patients (treated patients had an average IHSS score of 27.06 ± 9.98, untreated patients 26.90 ± 10.06, $p=1.000$), nor did the treated patients differ significantly from the untreated patients in their answers to the individual questions of the IHSS questionnaire. When correlating the total IHSS score with other questionnaires separately in treated patients (N=16) and untreated patients (N=21), all p-values were also significant, except for the total IHSS score and ESS in treated patients ($p=0.09$) and the total IHSS and HADS-A scores in treated patients ($p=0.06$). The cut-off for discrimination between control subjects and untreated IH patients is a score of 12.5 (specificity 0.95, sensitivity 0.98).

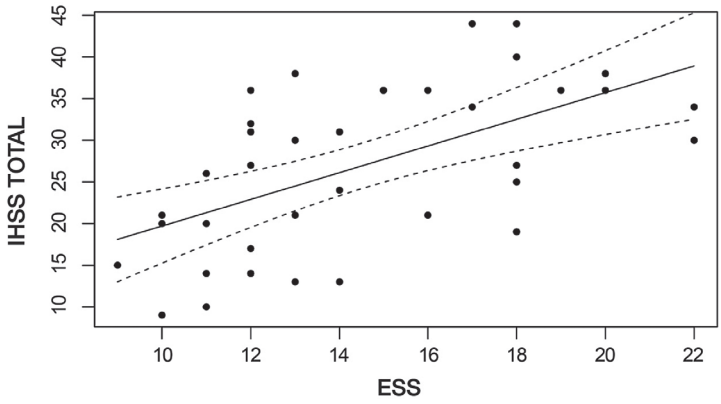

Figure 1 – Total Idiopathic Hypersomnia Severity Scale (IHSS) score vs. Epworth Sleepiness Scale (ESS) in our idiopathic hypersomnia cohort (N=37, ρ = 0.59, p=0.0001).

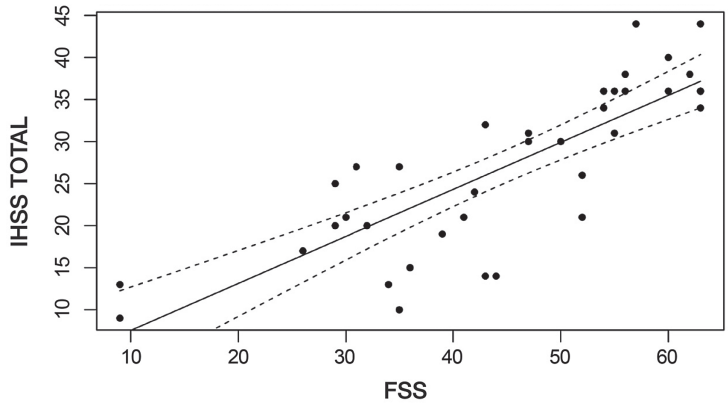

Figure 2 – Total Idiopathic Hypersomnia Severity Scale (IHSS) score vs. Fatigue Severity Scale (FSS) in our idiopathic hypersomnia cohort (N=37, ρ = 0.84, p<0.0001).

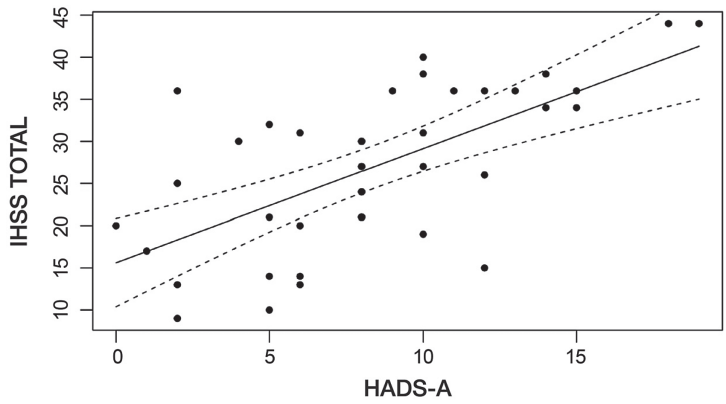

Figure 3 – Total Idiopathic Hypersomnia Severity Scale (IHSS) score vs. Hospital Anxiety and Depression Scale (HADS-A) in our idiopathic hypersomnia cohort (N=37, ρ = 0.64, p<0.0001).

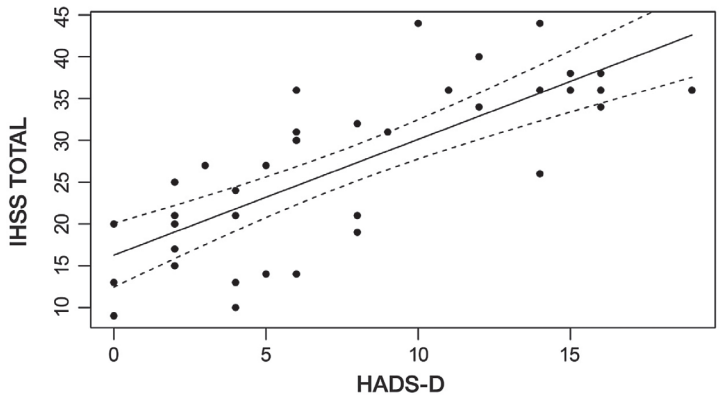

Figure 4 – Total Idiopathic Hypersomnia Severity Scale (IHSS) score vs. Hospital Anxiety and Depression Scale (HADS-D) in our idiopathic hypersomnia cohort (N=37, ρ = 0.79, p<0.0001).

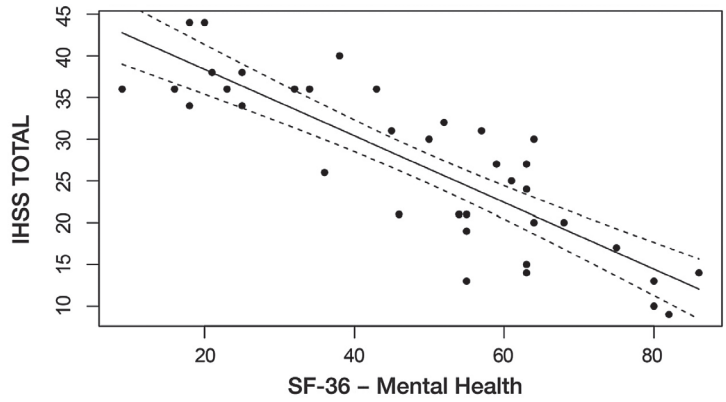

Figure 5 – Total Idiopathic Hypersomnia Severity Scale (IHSS) score vs. the Mental Health Component of SF-36 in our idiopathic hypersomnia cohort (N=37, ρ = –0.85, p<0.0001).

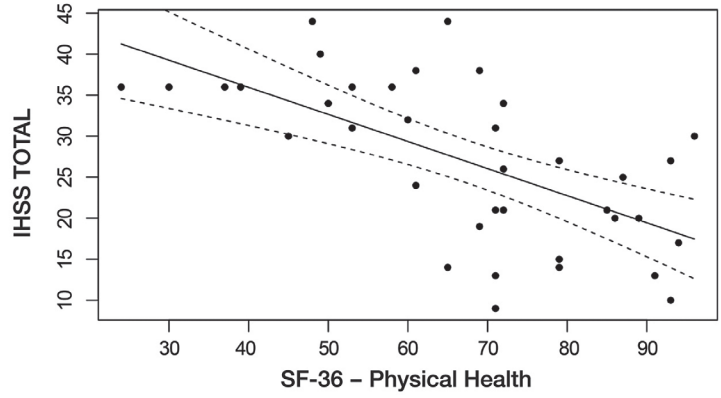

Figure 6 – Total Idiopathic Hypersomnia Severity Scale (IHSS) score vs. the Physical Health Component of SF-36 in our idiopathic hypersomnia cohort (N=37, ρ = –0.85, p<0.0001).

Discussion

This study demonstrated good psychometric properties of the Czech variant of IHSS in a cohort of patients with idiopathic hypersomnia from two sleep centres. Significant correlations of individual items and the total IHSS score were found, and the Cronbach α confirmed a high degree of internal consistency of the questionnaire and its good reliability. There is also a significant correlation between the total IHSS score and the Epworth Sleepiness Scale, the Fatigue Severity Scale, as well as selected scales assessing anxiety and depression (HADS-A, HADS-D) and an abbreviated version of the Quality of Life Questionnaire (SF-36).

IHSS distinguishes patients with IH well from healthy control subjects and describes in a good balance the basic clinical symptoms (prolonged unrefreshing night-time sleep accompanied by sleep inertia, excessive daytime sleepiness, and decreased alertness during the day). The original validation study set the average IHSS score in patients at 26 points vs. the mean IHSS score in control subjects at 10.5 points (Dauvilliers et al., 2019). This corresponds to our findings of 27 points in the patient group vs. 6 points in healthy subjects. For a reliable cut-off score for discriminating between healthy controls and untreated patients with IH, the French authors set a cut-off score of ≥ 22, our study admits a cut-off score of 12.5, which means that in our case the control group reported lower sleepiness. This difference may be due to the difference in control group design. The original French study included control subjects from the age of 16 who are expected to have a higher need for sleep, and these participants were included in the study on the basis of advertising and local communication networks. Most of our control subjects directly underwent polysomnographic examination to verify the normal quality of night-time sleep as part of another project. The psychometric properties of the IHSS scale confirm that it represents a reliable tool for determining the severity of diseases and its impact on daily functioning. There is no other scale or gold standard for determining the severity of idiopathic hypersomnia, so the other options for comparison are limited.

Due to the fact that the pathophysiology of this disease is not yet fully elucidated and reliable biomarkers are not available, the diagnosis of IH is determined *per exclusionem*, i.e. on the basis of the exclusion of other sleep disorders, such as narcolepsy type 2, atypical forms of depression, mild breathing disorder during sleep, behaviourally induced syndrome of insufficient sleep and phenotype of so-called long-sleepers (Billiard and Sonka, 2016, 2022). Expert studies consistently document the disabling nature of idiopathic hypersomnia and sporadic longitudinal follow-ups confirm the long-term persistence of specific phenotypes of this disease (Nevsimalova et al., 2021). From the diagnostic point of view, a comprehensive approach is therefore necessary (i.e. a detailed medical history, physical examination, actigraphy, polysomnographic examination, multiple latency test and sleep duration ad libitum), which should also include the above-mentioned scale of disease severity that makes it possible to distinguish idiopathic hypersomnia from the other forms

of daytime sleepiness mentioned above and to generally quantify the impact of the disease on normal daily activities. The IH severity scale makes it possible to assess the treatment effect over time as well as to compare the results of different research studies. At the same time, the Czech variant of IHSS will enable the involvement of Czech patients in international research projects.

An original study by French authors found a decrease in the IHSS score after starting treatment. In this study, the authors had the opportunity to compare the IHSS scores in the same patients before and after starting treatment (Dauvilliers et al., 2019). Unfortunately, our cohort did not allow such a pair testing option. Due to the low incidence of IH in Czech Republic, it was not possible to create a sufficiently large group of new patients in a reasonable time frame that could be tested after the start of treatment. The severity of symptoms of both our treated and untreated patients who are monitored longitudinally remained within the range of moderate symptoms. There are probably several reasons for the comparable IHSS score in both groups. Untreated patients were in most cases not at the beginning of their illness or had not been recently diagnosed – they were patients who had previously decided not to take medication, mostly due to mild symptom severity. In addition, most of them had the possibility of an optimal sleep-wake regime, which is another reason why they did not need pharmacotherapy in the long-term and evaluated their clinical condition as rather mild. Furthermore, this could also be affected by COVID-19 pandemic, during which the study was conducted. As the sleepiness, as well as other clinical manifestations could be affected by regime, most of the patients had a possibility of daytime naps and prolongation of night-time sleep to meet their needs. In particular, patients working remotely reported an overall lower intensity of sleepiness during this time. Conversely, the persistence of moderately high IHSS scores in treated patients who can be expected to have more severe clinical symptoms prior to initiation of treatment may have been influenced by the fact that treatment had only a partial effect in them. Residual symptoms in patients with idiopathic hypersomnia have been repeatedly described in the literature despite off-label pharmacotherapy (Trotti et al., 2020; Schneider et al., 2023).

The limitation of this validation study is the low number of patients; however, it is a rare disease, which does not allow the cohort to be increased within the Czech Republic. The unequal representation of men and women is due to the higher incidence of idiopathic hypersomnia in women (Vernet and Arnulf, 2009; Arnulf et al., 2019; Nevsimalova et al., 2021). This is also evidenced by our clinical experience.

Conclusion

In conclusion, IHSS represents a short, internally consistent and easy-to-apply clinical tool for determining the severity of clinical symptoms of idiopathic hypersomnia and their consequences. Previous studies have also shown the suitability of its use to monitor the effect of treatment.

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