# Sleep Quality and Its Associated Factors in Patients With Chronic Hepatitis C Receiving Antiviral Therapy

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#### **■** Learner objectives:

- -- The learners will be able to know the background, method, and the participants in this study.
- -- The learners will be able to know the sleep quality in patients with chronic hepatitis C receiving antiviral therapy.
- **Conflict of interest statement**: no claims.
- **Employer**: I-Shou University, Kaohsiung, Taiwan
- This study was granted by Ministry of Science and Technology in Taiwan

## Background

- The standard therapy for hepatitis C is injection of pegylated interferon and oral Ribavirin. Patients have to receive the combination therapy for 16 to 24 weeks, depending on patients' responses.
- Patients who are hepatitis C receiving antiviral therapy experience various discomfort symptoms.
   Poor sleep quality is found to be the often occurred side effect.
- The symptom does not only impact patients' quality of lives, but also result in incompliance with or early withdrawal from the therapy.

## Purpose

■ To explore the sleep quality and its associated factors in patients with chronic hepatitis C receiving antiviral therapy.

#### Method

- A longitudinal study was designed to conduct at an outpatient clinic in a teaching hospital.
- The sleep quality and its associated factors were collected before the therapy and once per month until the therapy completed, depending on patients responses to the medications.
- The questionnaire of Pittsburg sleep quality index
   (PSQI) was used to measure the patients' sleep quality.
- The patients' demographic and laboratory data were also collected.

## Questionnaires-1

- The questionnaire of Pittsburg sleep quality index (PSQI) contains 19 self-rated items and seven dimensions on a 0-3 scale. The higher scores indicated worse sleep quality.
- The seven dimensions include subjective sleep quality, sleep latency (the time from lying down for sleep to the start of actual sleep), sleep duration, habitual sleep efficiency, sleep disturbance, and use of sleeping medication.
- The Cronbach's alpha of PSQI was 0.79 (Tzeng et al., 2012).

# Questionnaires-2

- The patients' demographic data include age, gender, marital status, educational level, and occupation.
- The laboratory data were the viral genotype, hemoglobin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and rapid virologic response (RVR).

# **Participants**

- The inclusion criteria were: (1) The patients' serum tests with Anti-HCV (+) lasted for more than 6 months; and (2) The patients with hepatitis C were treated with pegylated Interferon and/or Ribavirin.
- The exclusion criteria included: (1) The patients under age 18; (2) Co-infected with HIV; (3) The patients with substance abuse and/or alcoholism; and (4) The individuals have hypo or hyper-thyroidism from past medical history.

## **Data Analysis**

- The data were analyzed using statistical product and service solutions (SPSS) version 19.
- Descriptive statistics were used to calculate the demographic characteristics and the mean scores of sleep quality at baseline and over the 6 months follow-up period.
- Paired t tests was used to analyze the global PSQI scores, hemoglobin, GOT (AST), and GPT (ALT) between the baseline and following 6 months in this study.

#### Results-1

#### Participants' Demographic

- A total of 29 patients, including 10 females and 19 males was recruited in this study.
- > Their average age was 55 years (ranging from 35 to 74 years).
- The genotypes of hepatitis C virus are as follows:
  type 1 (2, 1.1%), 1a (2, 1.1%), 1b (11, 5.8%),
  type 2a (10, 5.3%), 2b (3, 1.6%), and 6 (1, 0.5%),
  respectively.

# Subjective sleep quality

- During the past month, how would you rate your sleep quality overall?
- Score 0= very good, 1=fairly good, 2=fairly bad,3=very bad

Time	0 (n, %)	1 (n, %)	2 (n, %)	3 (n, %)
Baseline	4 (13.8)	14 (43.8)	5 (17.2)	6 (20.7)
1 <sup>st</sup> month	3 (11.1)	10 (37.0)	12 (44.4)	2 (7.4)
2 <sup>nd</sup> month	1 (3.7)	13 (48.1)	7 (25.9)	6 (22.2)
3 <sup>rd</sup> month	3 (13.0)	10 (43.5)	6 (26.1)	4 (17.4)
4 <sup>th</sup> month	3 (13.0)	8 (34.8)	10 (43.5)	2 (8.7)
5 <sup>th</sup> month	5 (22.7)	6 (27.3)	6 (27.3)	5 (22.7)
6 <sup>th</sup> month	0 (0)	10 (62.5)	3 (18.8)	3 (18.8)

## Sleep latency

- The time from lying down for sleep to the start of actual sleep.
- During the past month, how long (in minutes) has it usually taken you to fall asleep each night?
- How often have you had trouble sleeping because you cannot get to sleep within 30 minutes.

Time	0 (n, %)	1 (n, %)	2 (n, %)	3 (n, %)
Baseline	3 (10.3)	9 (31.0)	10 (34.5)	7 (24.1)
1st month	8 (27.6)	6 (20.7)	9 (31.0)	6 (20.7)
2 <sup>nd</sup> month	9 (31.0)	8 (27.6)	4 (13.8)	8 (27.6)
3 <sup>rd</sup> month	13 (44.8)	7 (24.1)	5 (17.2)	4 (13.8)
4 <sup>th</sup> month	13 (44.8)	7 (24.1)	3 (10.3)	6 (20.7)
5 <sup>th</sup> month	12 (41.4)	5 (17.2)	7 (24.1)	5 (17.2)
6 <sup>th</sup> month	16 (55.2)	4 (13.8)	4 (13.8)	5 (17.2)

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#### **Sleep duration**

- During the past month, how many hours of actual sleep did you get at night?
- Score 0: >= 7 hours, 1: 6-6.9 hours, 2: 5-5.9 hours, 3: <=4.9 hours</p>

Time	0 (n, %)	1 (n, %)	2 (n, %)	3 (n, %)
Baseline	11 (45.8)	9 (37.5)	2 (8.3)	2 (8.3)
1 <sup>st</sup> month	14 (63.6)	6 (27.3)	1 (4.5)	1 (4.5)
2 <sup>nd</sup> month	12 (52.2)	5 (21.7)	3 (13.0)	3 (13.0)
3 <sup>rd</sup> month	10 (55.6)	3 (16.7)	4 (22.2)	1 (5.6)
4 <sup>th</sup> month	10 (52.6)	3 (15.8)	3 (15.8)	3 (15.8)
5 <sup>th</sup> month	10 (58.8)	3 (17.6)	1 (5.9)	3 (17.6)
6 <sup>th</sup> month	5 (38.5)	4 (30.8)	1 (7.7)	3 (23.1)

#### Habitual sleep efficiency

- Calculate (Number of hours /Number of hours spent in bed )x100= %
- > Score 0: >= 85%, 1: 75-84%, 2: 65-74%, 3: <=64%

Time	0 (n, %)	1 (n, %)	2 (n, %)	3 (n, %)
Baseline	12 (52.2)	5 (21.7)	2 (8.7)	4 (17.4)
1st month	13 (59.1)	3 (13.6)	0 (0)	6 (27.3)
2 <sup>nd</sup> month	13 (56.5)	2 (8.7)	1 (4.3)	7 (30.4)
3 <sup>rd</sup> month	11 (61.1)	1 (5.6)	0 (0)	6 (33.3)
4 <sup>th</sup> month	13 (68.4)	0 (0)	1 (5.3)	5 (26.3)
5 <sup>th</sup> month	7 (46.7)	3 (20.0)	2 (13.3)	3 (20.0)
6 <sup>th</sup> month	7 (53.8)	1 (7.7)	0 (0)	5 (38.5)

#### Sleep disturbance-1

- During the past month, how often have you had trouble sleeping because you
- > ...cannot get to sleep within 30 minutes
- > ...wake up in the middle of the night or early morning
- > ...have to get up to use the bathroom
- ...cannot breath comfortably
- ...cough or snore loudly
- > ... feel too cold or feel too hot
- > ...had had dreams
- > ...have pain

#### Sleep disturbance-2

- Score 0: not during the past month, 1: less than once a week,2: once or twice a week, 3: three or more times a week
- Add the scores for the above questions

■ Sum scores: 0: 0 1: 1-9 2: 10-18 3:19-27

Time	0 (n, %)	1 (n, %)	2 (n, %)	3 (n, %)
Baseline	0 (0)	20 (69.0)	9 (31.0)	0 (0)
1 <sup>st</sup> month	3 (10.3)	18 (62.1)	8 (27.6)	0 (0)
2 <sup>nd</sup> month	2 (6.9)	18 (62.1)	9 (31.0)	0 (0)
3 <sup>rd</sup> month	6 (20.7)	16 (55.2)	6 (20.7)	1 (3.4)
4 <sup>th</sup> month	6 (20.7)	14 (48.3)	9 (31.0)	0 (0)
5 <sup>th</sup> month	9 (31.0)	14 (48.3)	6 (20.7)	0 (0)
6 <sup>th</sup> month	13 (44.8)	12 (41.4)	4 (13.8)	0 (0)

## Use of sleeping medication

- During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?
- Score 0: not during the past month, 1: less than once a week,2: once or twice a week, 3: three or more times a week

Time	0 (n, %)	1 (n, %)	2 (n, %)	3 (n, %)
Baseline	20 (69.0)	4 (13.8)	0 (0)	5 (17.2)
1st month	16 (59.3)	3 (11.1)	1 (3.7)	7 (25.9)
2 <sup>nd</sup> month	17 (63.0)	1 (3.7)	0 (0)	9 (33.3)
3 <sup>rd</sup> month	11 (47.8)	3 (13.0)	3 (13.0)	6 (26.1)
4 <sup>th</sup> month	10 (43.5)	3 (13.0)	4 (17.4)	6 (26.1)
5 <sup>th</sup> month	9 (42.9)	2 (9.5)	3 (14.3)	7 (33.3)
6 <sup>th</sup> month	5 (31.3)	1 (6.3)	2 (12.5)	8 (50.0)

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## **Daytime dysfunction-1**

- During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?
- Score 0: not during the past month, 1: less than once a week,2: once or twice a week, 3: three or more times a week
- During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?
- Score 0: no problem at all, 1: only a very slight problem,2: somewhat of a problem, 3: a very big problem
- Add the scores for above 2 questions

# **Daytime dysfunction-2**

■ Sum scores: 0: 0 1: 1-2 2: 3-4 3: 5-6

Time	0 (n, %)	1 (n, %)	2 (n, %)	3 (n, %)
Baseline	17 (58.6)	7 (24.1)	5 (17.2)	0 (0)
1 <sup>st</sup> month	17 (58.6)	3 (10.3)	7 (24.1)	2 (6.9)
2 <sup>nd</sup> month	18 (62.1)	2 (6.9)	6 (20.7)	3 (10.3)
3 <sup>rd</sup> month	16 (55.2)	6 (20.7)	4 (13.8)	3 (10.3)
4 <sup>th</sup> month	12 (41.4)	11 (37.9)	4 (13.8)	2 (6.9)
5 <sup>th</sup> month	16 (55.2)	4 (13.8)	9 (31.0)	0 (0)
6 <sup>th</sup> month	17 (58.6)	3 (10.3)	9 (31.0)	0 (0)

## **Global PSQI**

- Add the seven dimensions scores together.
- The higher scores indicated worse sleep quality.
- PSQI >5 indicates poor sleep quality.

Time	Mean	SD
Baseline	7.42	3.92
1 <sup>st</sup> month	7.36	4.50
2 <sup>nd</sup> month	8.29	5.11
3 <sup>rd</sup> month	7.50	5.48
4 <sup>th</sup> month	7.94	5.80
5 <sup>th</sup> month	8.07	5.24
6 <sup>th</sup> month	10.00	5.59

#### Results-2

- There is no significant difference between males and females in global PSQI.
- The paired t test revealed a significant difference between baseline and the  $6^{th}$  month in global PSQI (t = 0.68, p = .014).
- The t test showed that there are significant differences between pre-test and post-test in hemoglobin (t = 9.01, p < .01), GPT (t = 5.92, p < .01), and GOT (t = 4.94, p < .01).

#### Discussion

- The results may be generalized to a small population.
- The patients with hepatitis C had poor sleep quality at baseline (M=7.42, SD=3.92) and was getting worse after receiving antiviral therapy, especially the 6<sup>th</sup> month (M=10.0, SD=5.59).
- Sixty nine percent of patients have no need to take sleeping pills at baseline. When the patients started receiving the therapy, they had to take medicines 3 or more times a week to help them sleep.
- Further research may recruit a control group (without treatment) for comparing the difference in global PSQI.

# Thank you for your attention! Questions?