Effects of China-Germany Follow Up Systems on Ventilator Therapy in Patients with Obstructive Sleep Apnea Syndrome

Yujie Chen*, Linglin Yang, Yong Li, Qinze He, Yi Wang

Sleep Centre, Sichuan Fourth People's Hospital, Sichuan, China

Abstract: *Objective:* To investigate the effects of different follow-up systems in China and Germany on ventilator therapy in patients with obstructive sleep apnea syndrome. *Method:* From March 2013 to October 2015, three hundred patients with moderate to severe obstructive sleep apnea syndrome and those who are suitable for ventilator treatment were followed up according to the follow-up system of both China and Germany. The follow-up was carried out for one year to compare the rate of loss to follow-up, ventilator therapy compliance, treatment effect, ventilator side effects and others in the two groups of patients. Statistical analysis was performed using x^2 test, $P<0.05$ for the difference was statistically significant. *Results:* The rate of loss to follow-up in the German group was lower than that in the Chinese group. The compliance of the German group with respiratory therapy was lower than that of the Chinese group. The side effects of ventilator treatment were lower than those in the Chinese group ($P<0.05$). *Conclusion:* The German follow-up system is more effective than the Chinese follow-up system in improving the compliance and effectiveness of ventilator therapy in patients with obstructive sleep apnea syndrome.

1 Introduction

Obstructive sleep apnea syndrome (OSAS) is a disease with high prevalence, a potentially dangerous disease. It is mainly manifested by snoring during sleep accompanied by apnea and superficial respiration, recurrent hypoxemia at night, hypercapnia and sleep structure disorder which leads to daytime sleepiness, increase work and traffic accidents. It can cause cardiovascular and pulmonary vascular complications and multiple organ dysfunction which seriously affects the quality of life and life of patients[1]. However, because OSAS is less familiar to us, most patients have insufficient understanding of the disease and lack of knowledge (traditional beliefs even suggest that snoring is a good example of sleep). Thus, patients and their families have not received enough attention, and the use of non-invasive ventilators has a high cost of treatment. It is difficult for patients to receive treatment or difficult to receive treatment for a long time. Poor compliance has a significant impact on disease control. Whereas, German sleep medicine developed much earlier. In 1998, it obtained the qualification of "sleep medicine" while in 2004, it gradually matured. Due to the higher level of awareness of OSAS in the German and a more comprehensive German follow-up system, patients have higher acceptance of treatment and thus, the incidence of complications and mortality are reduced. Therefore, this paper compares the OSAS patients who are treated with ventilator in the follow-up system between China and Germany to investigate the effects of both follow-up systems on ventilator therapy in patients with OSSAS.

2 Study subjects

The moderate-severe adult patients diagnosed with OSAS were monitored by the polysomnography (PSG) from the Sleep Respiratory Diagnosis and Treatment Centre of the Fourth People's Hospital of Sichuan Province and the Sleep Centre of the German Hospital, from March 2013 to October 2015. The Chinese OSAS diagnostic criteria refer to the guidelines for the diagnosis and treatment of obstructive sleep apnea syndrome (2011 revision)[1] while the German OSAS diagnostic criteria refer to the 2014 ACP (American College of Physicians) clinical guidelines for adult obstructive sleep apnea therapy[2] in selecting a total of 300 OSAS patients with complete information and comply with inclusion and exclusion criteria, and conducted CPAP pressure titration.

2.1 Inclusion criteria

1.) Moderate and severe patients who meet the OSAS diagnostic criteria; 2.) Patients who have undergone CPAP pressure titration and have purchased a non-invasive ventilator or undergoing long-term family CPAP treatment through a ventilator manufacturer's rental ventilator; 3.) Age ≥ 18 years old.

2.2 Exclusion criteria

1.) Patients who are not suitable or should be treated with mechanical ventilation with caution: I) X-ray examination has determined large lung bullae, pneumothorax or mediastinal emphysema. II) Blood pressure is significantly reduced, or there is significantly circulating blood loss. III) Acute otitis media, rhinitis or sinusitis infection is uncontrollable. IV) Recurrent episodes of nosebleeds. 2.) Simple snoring or mild OSAHS patients. 3.) Patients diagnosed with obese hypoventilation syndrome. 4.) Simple central sleep apnea patients. 5.) Patients who have undergone surgery for uvulopalatopharyngoplasty. 6.) Patients with severe claustrophobia. 7.) Patients who taking benzodiazepines, barbiturates, sedatives and other drugs which may affect sleep. 8.) Patients who suffering from benign prostatic hyperplasia, diabetes insipidus and other diseases that cause nocturia and other diseases.

3 Methods

3.1 The follow-up system of the Sleep Centre of Sichuan Fourth People's Hospital

1.) Guidance on disease-related knowledge, ventilator therapy and side effects before CPAP treatment as well as experience sharing by patients with successful therapy; 2.) Special telephone follow-up by a respiratory therapist from the sleep centre to follow-up with patients for one week, one month, three months, six months and 12 months after the first diagnosis. Telephone follow-up content: I) To explain the mechanism of the disease, the process of disease development, the main clinical manifestations and complications, the standard examination and treatment methods, the role of ventilator treatment to patients and their families. II) To understand the patient's use of the ventilator and to guide the adjustment of the ventilator parameters including pressure, humidity, temperature, extended time, trigger sensitivity, mask wear, cleaning, simple maintenance and discomfort during use or abnormal response via the remote network control system. III) The patient actively communicates with the respiratory therapist, and the respiratory therapist guides the patient based on the problem faced. 3.) Establish a respiratory rehabilitation clinic: doctors and respiratory therapist can conduct face-to-face interviews and guidance with OSAS patients receiving ventilator therapy.

3.2 German follow-up system[3]

1) Guidance on disease-related knowledge, ventilator treatment and side effects before CPAP treatment as well as experience sharing by patients with successful therapy; 2) Patients with family therapy return to the hospital after a week for face-to-face interviews. The interview contents including improvement of the patient's self-symptoms, side effects of the ventilator, feedback from the bed partner, data collection and evaluation of the ventilator; 3) The insurance company conducts telephone follow-up with ventilator treated patient during the first month, third months, sixth months and twelfth months; 4) The ventilator manufacturer performs regulator maintenance on the ventilator: the maintenance time is three months, six months and twelve months.

All patients were monitored by at least one overnight standard polysomnography. All patients included in the study were recorded for age, gender and BMI on the day of monitoring.

Assessment of sleepiness: Patients were assessed for daytime sleepiness based on the Epworth scale.

Definition of compliance: Most foreign researchers currently have good compliance with no less than 4 hours of application per night. If it is applied at 70% or

more night, it is not limited to 4 hours.

Statistical analysis: SPSS 16.0 statistical software was used. Data were expressed as mean ± standard deviation. Group t-test was used for comparison between groups. P<0.05 was considered statistically significant.

4 Results

4.1 Comparison of the general situation of the two groups of patients was demonstrated in Table 1

Table 1. Comparison of the general conditions of the two groups of patients

	Chinese group n = 300	German group n = 300	P-value
Age	46.3 ± 14.3	43.4 ± 11.2	P > 0.05
Male (%)	87.1	83.5	P > 0.05
BMI	33.5 ± 7.2	32.6 ± 5.8	P > 0.05
AHI	48.7 ± 12.1	50.2 ± 13.6	P > 0.05
ESS score	11.2 ± 3.3	10.6 ± 2.8	P > 0.05

Note: The above data showed that there was no significant difference in age, BMI, AHI and ESS between the Chinese group and the German group (P > 0.05).

4.2 Comparison of loss to follow-up rates between the two groups was demonstrated in Table 2

Table 2. Comparison of loss to follow-up rates between the two groups

	Chinese group	German group	P-value
Loss to follow-up number (%)	12.3	6.3	P < 0.05

Note: The above data indicates that the number of patients who were treated with ventilator in the Chinese and German groups was lost to follow-up in China, there are 37 in China accounting for 12.3% of the total number, and there are 19 in Germany accounting for 6.3% of the total number. The difference in the rate of loss to follow-up was statistically significant (P < 0.05).

4.3 Comparison of ventilator usage time between the two groups of patients was demonstrated in Table 3

Table 3. Comparison of ventilator usage time between the two groups of patients

	Chinese group n = 267	German group n = 281	P-value
Hours	4.3 ± 1.3	6.7 ± 0.9	P < 0.05

Note: In the comparison of this table, the daily ventilator usage time of the two groups of patients was compared. Although the usage time of both groups reached the compliance index, the Chinese group had shorter ventilator usage time than the German group. Statistically significant (P < 0.05).

4.4 Comparison of weekly ventilator usage time between the two groups was demonstrated in Table 4

Table 4. Comparison of weekly ventilator usage time between the two groups

	Chinese group n = 267	German group n = 281	P-value
Number of days	4.2 ± 0.2	5.7 ± 1.3	P < 0.05

Note: In the comparison of this table, the number of days of ventilator usage time per week was compared between the two groups. The ventilator used in the Chinese group was shorter than the German group, and the difference was statistically significant (P < 0.05).

4.5 Comparison of clinical symptoms after ventilator therapy in both groups was demonstrated in Table 5

Table 5. Comparison of clinical symptoms after ventilator therapy in both groups

	Chinese group n = 267	German group n = 281	P-value
Snoring at night	36	41	> 0.05
Awakened	23	19	> 0.05
Daytime sleepiness	8	6	> 0.05
Morning sore throat	67	42	< 0.05
Morning headache	62	49	< 0.05
Nocturia	39	29	> 0.05

Note: In the comparison of this table, the improvement of clinical symptoms after ventilator therapy in the two groups was compared. The Chinese group had worse clinical symptoms than the German group, but only in the morning sore throat and morning headache. The difference was statistically significant (P < 0.05).

4.6 Comparison of ventilator side effects between the two groups was demonstrated in Table 6

Table 6. Comparison of ventilator side effects between the two groups

	Chinese group n = 267	German group n = 281	P-value
Local skin compression	48	23	< 0.05
Soft palatal air leak	82	41	< 0.05
Nasopharyngeal discomfort	69	61	> 0.05
CPAP pressure not suitable	54	31	< 0.05
Nighttime arousal	19	15	> 0.05
Snorting noise	56	12	< 0.05

Note: In the comparison of this table, the alternative used in the replacement of patients' ventilators were compared. The Chinese group was similar to the German group in terms of nasopharyngeal discomfort and nighttime arousal. The difference was not statistically significant (P > 0.05); Other aspects were significantly different from the German group, and it was statistically significant (P < 0.05).

5 Discussion

CPAP is currently one of the most effective treatments for moderate to severe OSAS. Comprehensive long-term management and follow-up system is required for OSAS patients. The diagnosis and initiation of CPAP therapy is only the first step. Ideally, an optimized disease management and follow-up system can identify patients who are unable to adhere to CPAP and the reason behind it. Increase compliance with ventilator therapy in OSAS patients can reduce the side effects of non-invasive ventilator.

This study compared the follow-up system between China and Germany to compare the loss to follow-up rate, compliance and effect of ventilator treatment, and side effects in patients with OSAS who were treated with a ventilator. From the enrolled cases, the basal levels of the two groups were consistent and comparable (Table 1).

From the rate of loss to follow-up in the two groups of Chinese and German patients receiving ventilator treatment, there are 37 people lost to follow-up in China, accounting for 12.3% of the total number of people while there are 19 people lost to follow-up in Germany, accounting for 6.3% of the total number of participants. There was a statistically significant difference in the rate of loss to follow-up between the two groups (P < 0.05) (Table 2). The reason for the loss to follow-up in China was due to the lack of telephone calls, 26 cases of no answer to the telephone, 2 cases of refusal to answer, 9 cases of treatment stopped because

of economic reasons, and a total of 37 cases were lost. In Germany, there are 15 cases of moving out from the original place of residence, and 4 cases were treatment stopped because of economic reasons, and a total of 19 cases were lost to follow-up. From the reasons for the loss to follow-up, we can see that the economic reasons are an important cause of poor compliance in China's OSAS patients. China is a developing country, and regional economic development is uneven. Thus the cost of ventilator purchase and maintenance, which is high could result in some patients being not able to receive the treatment. From the usage time of ventilator in the two groups of patients, despite the usage time of both groups reached the compliance index, the Chinese group had shorter ventilator usage time than the German group, the difference was statistically significant (P < 0.05) (Table 3). From the weekly ventilator usage time of the two groups of patients, the Chinese group had shorter ventilator usage time than the German group, and the difference was statistically significant (P < 0.05) (Table 4). From the improvement of clinical symptoms after ventilator use in the two groups of patients, although the clinical symptoms of the two groups of patients after using the ventilator were improved compared with the previous ones, the patients in the Chinese group were worse than the German group in terms of clinical symptoms improvement, but only in the morning. The difference was statistically significant in terms of morning sore throat and morning headache (P < 0.05) (Table 5). From the side effects of ventilator in the two groups, the Chinese group was similar to the German group in terms of nasopharyngeal discomfort and nighttime arousal, and the difference was not statistically significant (P > 0.05); other side effects were more obvious than the German group, and it is statistically significant (P < 0.05) (Table 6).

This study shows that follow-up can improve the patient's compliance with ventilator treatment. Firstly, in the long term, sleep apnea syndrome is not considered a disease. Most patients lack knowledge of the disease, patients and their families has not paid enough attention, and the use of non-invasive ventilator treatment costs is high. Thus, patients are difficult to receive treatment or difficult to adhere to long-term treatment. Thus the compliance is poor. Whereas, through regular follow-up, explanation of the disease mechanism, development process and complications of the disease to the patients and their families so that they fully understand the disease and the difficulties in the ventilator treatment process, immediately solve problems in the process of usage, assist the physician to adjust the parameters in time, improve the treatment plan, increase the patient comfort, and improve the patient's compliance. 2 Planned, forward-looking and targeted. Focusing on individual return visits, patients who are using non-invasive ventilators can improve the effectiveness of continuous treatment and improve patient compliance. Secondly, planned, prospective and targeted individual-oriented follow-up can improve the effect of continuous treatment and compliance of patient who are treated with non-invasive ventilator.

From this study, we found that German sleep medicine developed earlier, the system is more complete, and the follow-up system is more perfect. The diagnosis and treatment of OSAS in Germany have been included in the medical insurance system. Thus the OSAS patients in Germany have higher acceptance of treatment. The German follow-up system consists of three parts which are the hospital's specialists and nurses, medical insurance center follow-up personnel, and ventilator manufacturer maintenance personnel. Therefore, the German follow-up system can increase the compliance and effectiveness of ventilator treatment in OSAS patients and can reduce the side effects of ventilator treatment. At the same time, with the participation of ventilator manufacturers, ventilators and masks have got better regulated and maintained, thus reducing adverse effects during the ventilator use. The diagnosis and treatment of OSAS in Germany have been included in the medical insurance system, which has reduced the economic burden of patients to a certain extent and increased social awareness. Whereas China's sleep medicine started late, and the economic development in various regions is uneven. The population in China has a poor understanding of sleep diseases. The follow-up system varies from region to region and from hospital to hospital. Moreover, OSAS diagnosis and treatment are not included in the medical insurance system in most parts of China. Thus, patients have poor acceptance of OSAS ventilator treatment and a huge economic burden. Some patients are unable to receive treatment because of the expensive cost of the ventilator. In addition, China's ventilator manufacturers are a mixture of good and bad, which results in a certain impact on the patient's treatment. The follow-up system in the hospital was gradually improved after 10 years of development. The main person involved in the follow-up was specialists, nurses, and respiratory

therapists. Only in the past two years, health assistants were introduced, and respiratory rehabilitation clinics were established. The respiratory rehabilitation clinic is composed of a physician, a respiratory therapist, and a ventilator manufacturer. It can communicate face-to-face with the patient and perform basic regulation and maintenance of the patients' ventilators.

It is necessary to learn from the German follow-up system to improve our current follow-up system and accelerate the development of OSAS into the medical insurance system, increase social awareness, reduce the economic burden of patients, and decrease the complications caused by OSAS.

References

[1] Chinese Medical Association Respiratory Diseases Association of Sleep Respiratory Diseases Group. Guidelines for the diagnosis and treatment of obstructive sleep apnea-hypopnea syndrome (2011 revised edition). Chinese Journal of Tuberculosis and Respiratory Diseases, 2012, 35(1):9–12.

[2] Qaseem A, Dallas P, Owens DK, et al. Diagnosis of Obstructive Sleep Apnea in Adults: A Clinical Practice Guideline From the American College of Physicians[J]. Am Intern Med, 2014, 161(3):210–20.

[3] Fietze I, Penzel T, Alonderis A, et al. Management of obstructive sleep apnea in Europe[J]. Sleep Medicine, 2011, 12:190–7.