

# A retrospective study of Ganoderma Lucidum Spore Powder for patients with epilepsy

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## Abstract

This study firstly investigated the feasibility effect and safety of Ganoderma Lucidum Spore Powder (GLSP) for treating patients with epilepsy.

Eighteen eligible patients with epilepsy were included. They all received GLSP treatment for a total of 8 weeks. The primary outcome included weekly seizure frequency. The secondary outcomes consisted of each seizure episode, and quality of life, measured by the Quality of Life in Epilepsy Inventory-31 (QOLIE-31), as well as the adverse events (AEs).

After treatment, GLSP can significant reduce the weekly seizure frequency, compared with it before the treatment ( $P = .04$ ). However, GLSP did not exert promising effect in each seizure episode ( $P = .13$ ), and quality of life, measured by the QOLIE-31 scale ( $P = .11$ ). Additionally, only minor AEs occurred during the treatment period.

The results of this study showed that GLSP may be effective for reducing the weekly seizure frequency. Further studies are still needed to warrant this result.

**Abbreviations:** AEs = adverse events, GLSP = Ganoderma Lucidum Spore Powder, QOLIE-31 = Quality of Life in Epilepsy Inventory-31.

**Keywords:** effect, epilepsy, Ganoderma Lucidum Spore Powder

## 1. Introduction

Epilepsy is one of the most common chronic neurological conditions.<sup>[1–3]</sup> It is estimated that epilepsy affects 65 million people worldwide.<sup>[4]</sup> Of those populations, about 22% to 30% patients have drug-resistant epilepsy.<sup>[4,5]</sup> Although lots of studies have explored its mechanism and treatments, epilepsy is still difficult to control and prevent.<sup>[6]</sup> It has been reported that antiepileptic drugs are the primary treatment for the epilepsy.<sup>[5,6]</sup> However, serious adverse events (AEs) are often accompanied patients with long-term medications.<sup>[7–10]</sup> These AEs include allergies, cognitive and mood impairment, depression, memory loss, and increased risk of death.<sup>[9,10]</sup> Thus, alternative therapies with few AEs are still needed to treat such condition.

In the search for an alternative epilepsy therapy, Ganoderma Lucidum Spore Powder (GLSP) is a potential intriguing

candidate.<sup>[11–14]</sup> It has been reported that animal data have supported that the antiepileptic effect of GLSP in both in vivo and in vitro studies.<sup>[11–24]</sup> Presently, limited data of using GLSP in treating human epilepsy is available.<sup>[25]</sup> Thus, clinical studies are critically needed to investigate the safety and efficacy of GLSP in epilepsy. In this firstly retrospective study, we investigated the feasibility effects and safety of GLSP for the treatment in patients with epilepsy.

## 2. Methods

### 2.1. Ethics

This study was approved by the Ethical Committee of First Affiliated Hospital of Jiamusi University and Hongqi Affiliated Hospital of Mudanjiang Medical University. All participants signed informed consent.

### 2.2. Design

This study was conducted between December 2016 and November 2017 at First Affiliated Hospital of Jiamusi University and Hongqi Affiliated Hospital of Mudanjiang Medical University. It included 18 eligible patients with epilepsy. All patients received GLSP, 3 times daily for a total of 8 weeks.

### 2.3. Participants

This retrospective study included 18 eligible patients with epilepsy aged from 22 to 63 years old. All patients were reported more than 2 epilepsy attacks during the past 3 months with 2 episodes at least 24 hours intervals before the recruitment. Additionally, all patients underwent at least 1 antiepileptic drug before the study. The exclusion criteria applied to subjects who had brain tumors, abnormal functions of liver and kidney, history of drug or alcohol addiction, drug allergy history, and gestational or lactating women.

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**Table 1****Patient characteristic before the study.**

Characteristics	Value (n = 18)
Age, y	39.4 (15.3)
Race, Chinese	18 (100.0)
Sex	
Male	10 (55.6)
Female	8 (44.4)
Duration seizure, y	7.6 (3.3)
Weight, kg	61.8 (11.2)
Seizure types	
Systemic attack	3 (16.7)
Partial attack	11 (61.1)
Atypical attack	4 (22.2)
Weekly seizure frequency	3.1 (0.8)
Previous drugs used	
Carbamazepine	9 (50.0)
Valproic acid	5 (27.7)
Topiramate	3 (16.7)
Phenytoin	2 (11.1)
Phenobarbital	1 (5.6)

Data are present as mean  $\pm$  standard deviation or number (%).

## 2.4. Therapy schedule

All patients received GLSP, 1000 mg each time, 3 times daily, 7 days weekly for a total of 8 weeks. GLSP was manufactured by the Beijing Great Wall Pharmaceutical Factory with Batch number of B20050008.

## 2.5. Outcomes

The primary outcome was weekly seizure frequency. It was defined as average weekly seizure frequency during the past 4 weeks before the outcome measurement time. The secondary outcomes included seizure episode, and quality of life, measured by the Quality of Life in Epilepsy Inventory-31 (QOLIE-31).<sup>[26]</sup> Additionally, AEs were also recorded duration the treatment period. All primary and secondary outcomes were measured before and after the treatment in this study.

## 2.6. Statistical analysis

All data were analyzed by a professional statistician using SPSS Statistics 17.0 (IBM Corp., Armonk, NY). Nonparametric test was used to analyze the data before and after the treatment. Statistical significance was defined as  $P < .05$ .

## 3. Results

The characteristics of all 18 included patients are shown in Table 1. The mean age is 39.4 years. The mean duration of seizure

**Table 2****Primary outcome of weekly seizure frequency before and after treatment.**

Outcomes	Before treatment (n = 18)	After treatment (n = 18)
Weekly seizure frequency	3.1 (0.8)	2.4 (1.2)
Difference (range)	—	0.6 (0.3–1.0)
<i>P</i>	—	.04

Data are present as mean  $\pm$  standard deviation.

**Table 3****Each seizure episode and QOLIE-31 before and after treatment.**

Outcomes	Before treatment (n = 18)	After treatment (n = 18)	Difference (range)	<i>P</i>
Each seizure episode, min	15.3 (4.8)	12.8 (5.1)	-2.5 (-3.8, -1.1)	.13
QOLIE-31	55.8 (7.5)	60.4 (9.6)	4.6 (2.3, 6.7)	.11

Data are present as mean  $\pm$  standard deviation.

QOLIE-31 = Quality of Life in Epilepsy Inventory-31.

is 7.6 years. The seizure types included systemic attacks 3 (16.7%), partial attacks 11 (61.1%), and atypical attacks 4 (22.2%). The mean weekly seizure frequency was 3.1. Moreover, previously used medication consisted of carbamazepine 9 (50.0%), valproic acid 5 (27.7%), topiramate 3 (16.7%); phenytoin 2 (11.1%); and phenobarbital 1 (5.6%).

After treatment, GLSP exerted encouraging effect in weekly seizure frequency, compared with it before the treatment ( $P = .04$ , Table 2). However, GLSP did not show significant differences in each seizure episode ( $P = .13$ , Table 3), and quality of life, measured by the QOLIE-31 scale ( $P = .11$ , Table 3).

AEs are listed in Table 4. All AEs are mild. No death related to the treatment occurred in this study. The common frequencies of AEs included stomach discomfort, 4 (22.2%); nausea, 6 (33.3%); vomiting, 3 (16.7%); dizziness, 3 (16.7%); dry mouth, 3 (16.7%); diarrhea, 2 (11.1%); epistaxis, 1 (5.6%), and sore throat, 2 (11.1%).

## 4. Discussion

Previous studies have reported that GLSP may be used to treat many conditions, such as prostate cancer, breast cancer, as well as the epilepsy.<sup>[27–30]</sup> Unfortunately, no clinical study reported the effect and safety of GLSP for treating patients with epilepsy. Furthermore, lots of animal studies support GLSP for treating epilepsy, and have achieved promising effect.<sup>[11–24]</sup> The results of the previous animal study have demonstrated that GLSP can inhibit the expression of NF- $\kappa$ B in the brain, and N-cadherin in hippocampal neurons in epilepsy rats. However, it can increase the expression of neurotrophin-4 in hippocampal neurons.<sup>[11]</sup> The other study also found that GLSP has antiepileptic effects by inhibit the  $Ca^{2+}$  accumulated in epileptic hippocampal neurons, and it also can stimulate the expression of CaMK II $\alpha$ .<sup>[14]</sup> To our best knowledge, although no clinical studies have explored the effect of GLSP, the results of these animal studies indicate the potential of GLSP in the treatment of epilepsy.

This is the first study to retrospectively investigate the effect and safety of GLSP for treating patients with epilepsy. The results

**Table 4****Adverse events occurred during the treatment period.**

Adverse events	Value (n = 18)
Stomach discomfort	4 (22.2)
Nausea	6 (33.3)
Vomiting	3 (16.7)
Dizziness	3 (16.7)
Dry mouth	3 (16.7)
Diarrhea	2 (11.1)
Epistaxis	1 (5.6)
Sore throat	2 (11.1)

Data are present as number (%).

found that GLSP can significantly reduce the weekly seizure frequency. However, it cannot decrease each seizure episode; and improve the quality of life in patients with epilepsy. It may be because a small number of patients included and relative short term of GLSP therapy in this study.

This study has three limitations. First, the sample size was quite small, and no control group was applied in this study. Thus, this study just explored the feasibility effect and may provide limited evidence for clinical practice. Second, the treatment period is only 8 weeks, and it is relative short, which may affect the real effect of GLSP for the treatment of epilepsy. Third, this study did not include follow-up assessments after the treatment cessation. Therefore, future studies should provide more powerful evidence with the design of randomized controlled trial, and longer treatment period and follow-up.

## 5. Conclusion

The results of this study demonstrated that GLSP may help to reduce the weekly seizure frequency in patients with epilepsy.

## Author contributions

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**Funding acquisition:** Li-hua Wang.

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