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# Safety Study of Monosialotetrahexosylganglioside Sodium in the Treatment of Stroke

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**Abstract:** *Objective*: To retrospectively analyze the safety and efficacy of monosialotetrahexosylganglioside sodium (GM1) in the treatment of stroke, and to provide a reference for clinical rational drug use. *Methods*: This study was a multicenter, single-arm, retrospective, observational study, which recruited stroke patients who were treated with GM1 from January 1, 2020, to December 31, 2023, as the research subjects, analyzed their adverse events and grades, and performed chi-square test and t-test on NIHSS scores and Barthel before and after intervention. Compare the scores before and after. *Results*: A total of 4405 patients were enrolled, and the NIHSS score of the patients decreased and the Barthel score increased after GM1 intervention, and there was a significant statistical difference before and after intervention ($P < 0.05$). A total of 1635 patients had adverse events, and 99.4% were mild, and severe was not seen. *Conclusion*: In this study, GM1 has high safety and significant efficacy in the treatment of stroke, and results suggest potential for clinical application, subject to further validation.

**Keywords:** Stroke; Tetrahexose ganglioside monosialic acid; Safety; Efficacy; Adverse events

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## 1. Introduction

Stroke refers to acute cerebrovascular disease caused by rupture or blockage of cerebral blood vessels, which ranks first among the causes of disability and death in China, with a rapid course and high fatality rate, and a serious poor prognosis is often seen in significant decline in language, motor and cognitive functions. In order to improve the quality of life of patients, therapeutic intervention is necessary for trunk muscle strength, balance and control of stroke patients. However, the current rehabilitation treatment process is mostly several years or even more than ten years, which is a heavy financial and mental burden for patients and their families. Based on the above, the research and development of some drugs to assist in the rehabilitation process has been put on

the agenda in the industry. Monosialotemhexosylganglioside (GM1) is one of the cell membrane components of mammals, which is mainly extracted from pig brain and has the potential to promote the repair of central nervous system injury. GM1 is the highest content in the central nervous tissue, which can effectively slow down the process of neurodegeneration, so that the damaged central nervous system can be repaired, and has an important regulatory role in the generation and regeneration of neurons.

In recent years, with the widespread application of the drug, adverse events have occurred frequently, but the treatment measures have been rarely reported, especially when the patient has dyspnea, anaphylactic shock and symptoms other than the adverse events indicated in the drug instructions, how to quickly and standardize the rescue treatment is particularly important, which can directly affect the health and life safety of the patient.

Therefore, this study solicited a retrospective and descriptive survey of stroke patients who used GM1 from January 1, 2020, to December 31, 2023, to provide a reference for the rational use of GM1 in the clinical treatment of stroke.

## 2. Data and methods

### 2.1. General information

This study is a multicenter, single-arm, retrospective, descriptive study. A total of 4405 stroke patients who received GM1 intervention in different hospitals from January 1, 2020, to December 31, 2023, were recruited and their clinical data were retrospectively analyzed. Inclusion criteria: (1) Language function deterioration, some facial and limb sensory dysfunction, symptoms for more than 24 hours, and CT and other imaging clinical examination results are stroke; (2) Previous use of GM1. Exclusion Criteria: (1) Patients who are allergic to GM1; (2) The body is currently accompanied by serious diseases of important organs such as heart, liver, and lungs; (3) Patients who are currently accompanied by mental illness and whose degree of mental abnormality cannot be graded [1,2].

### 2.2. Information collection

The main data information collected is as follows:

(1) Basic information: gender, age, height, weight, BMI;

(2) Disease diagnosis and past history information: including various clinical diagnosis medical records and reports, drug use and allergy history;

(3) Medication information: GM1 start time, administration method, intake medium, intake dose, infusion rate, combination medication, intake end time, etc.;

(4) Adverse events: specific time of occurrence and disappearance, affected organs and specific symptoms, degree of grading, what kind of intervention measures, etc.;

(5) Efficacy evaluation information: NIHSS and Barthel Index before and after treatment.

#### 2.3. Statistical analysis

All statistical analyses were performed using R4.3.2, and the median, interquartiles, minimum, maximum, mean and standard deviation were used for the quantitative variables, and the number and proportion of patients were used for the qualitative variables. The evaluation of intervention effect describes the frequency and composition ratio of the indicators. The NIHSS score before and after the intervention was compared using the paired t-test

method, and the Barthel Index before and after the intervention was compared using the McNemar test, and the statistical criterion was $p < 0.05$ [3].

# 3. Results

## 3.1. Demographic characteristics of patients

In this study, a total of 4411 stroke patients who were treated with GM1 between January 1, 2020, and December 31, 2023, were collected, and a total of 6 patients were found to be excluded because their data did not meet the requirements, and finally, 4405 patients were included for analysis [4]. Among them, there were 2,701 male patients and 1,704 female patients, with an average age of 59.1 years, an average height of 168.0cm, a weight of 67.2kg, and a BMI of 23.7. The results are shown in **Table 1**.

**Table 1.** Demographic characteristics of patients

| **Number of patients included** | ***N* = 4405** |
|---|---|
| Age | |
| The mean ± standard deviation | 59.1 ± 11.9 |
| Range | 16.8–97.4 |
| Median (Q1–Q3) | 59.6 (52.0–66.9) |
| Gender | |
| Man | 2701 (61.3) |
| Woman | 1704 (38.7) |
| Height (cm) | |
| The mean ± standard deviation | 168.0 ± 7.6 |
| Min-Max | 142.0-191.0 |
| Median (Q1–Q3) | 169.0 (162.0–174.0) |
| Weight (kg) | |
| The mean ± standard deviation | 67.2 ± 11.4 |
| Min-Max | 40.0–168.0 |
| Median (Q1–Q3) | 68.0 (60.0–75.0) |
| BMI | |
| The mean ± standard deviation | 23.7 ± 3.2 |
| Min-Max | 14.5–55.4 |
| Median (Q1–Q3) | 23.6 (21.8–25.6) |

## 3.2. Patient's disease diagnosis and anamnesis information

Among the 4405 patients, 3440 patients were diagnosed with ischemic stroke, accounting for 78.1%, and 965 patients were diagnosed with hemorrhagic stroke, accounting for 21.9%. Sixteen of all patients, accounting for 0.4%, had a history of drug allergy. The results are shown in **Table 2** and **Figure 1**.

**Table 2.** Diagnostic information and drug allergy history [*n*(%)]

| Anamnes/allergy history | Number of people (percentage) |
|---|---|
| Past history | |
| Hemorrhagic stroke | 965 (21.9) |
| Ischemic stroke | 3440 (78.1) |
| History of drug allergy, *n*(%) | |
| Be | 16 (0.4) |
| Not | 4389 (99.6) |

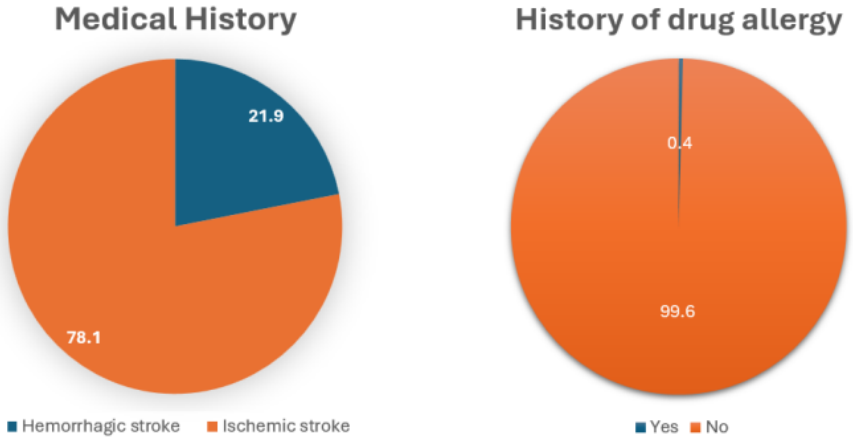


**Figure 1.** Diagnostic information and drug allergy history.

## 3.3. Patient medication information

The average number of days GM1 was 11.8 days in the included studies. A total of 4241 cases (96.3%) were mainly intravenous infusion, and 164 cases (3.7%) were intramuscular injection. Among the patients with intravenous infusion, 4041 patients received GM1 solvent, were 0.9% sodium chloride injection, accounting for 95.3%. There were 200 patients with 5% glucose injection as the solvent, accounting for 4.7%. Among the patients with intravenous infusion, there were 337 patients with a GM1 infusion time of 0–40 minutes, 2581 patients with 40-60 minutes, 1095 patients with 60-90 minutes, and 228 patients with more than 90 minutes. Among all patients, there were 130 patients with GM1 doses of 0-20 mg/day, 1748 patients with 20-80 mg/day, and 2527 patients with more than 80 mg/day. Among all patients, 3886 patients were treated alone, accounting for 88.2%; 519 cases were combined with drugs, accounting for 11.8%. The results are shown in **Table 3** and **Figure 2**.

**Table 3.** Patient medication information table

| **Medication information** | |
|---|---|
| Days of GM1 medication (days) | |
| The mean ± standard deviation | 11.8 ± 8.3 |
| Min–Max | 1.0–90.0 |
| Median (Q1–Q3) | 8.0 (7.0–14.0) |
| GM1 dosage mode | |
| Intravenous drip | 4241 (96.3) |
| intramuscular injection | 164 (3.7) |
| GM1 drug solvent | |
| 0.9% sodium chloride injection | 4041 (95.3) |
| 5% glucose injection | 200 (4.7) |
| GM1 instillation time | |
| 0–40 minutes | 337 (7.9) |
| 40–60 minutes | 2581 (60.9) |
| 60–90 minutes | 1095 (25.8) |
| More than 90 minutes | 228 (5.4) |
| GM1 dosage (mg/day) | |
| 0–20 | 130 (3.0) |
| 20–80 | 1748 (39.6) |
| > 80 | 2527 (57.4) |
| Combination medication | |
| Medication alone | 3886 (88.2) |
| Combination medication | 519 (11.8) |

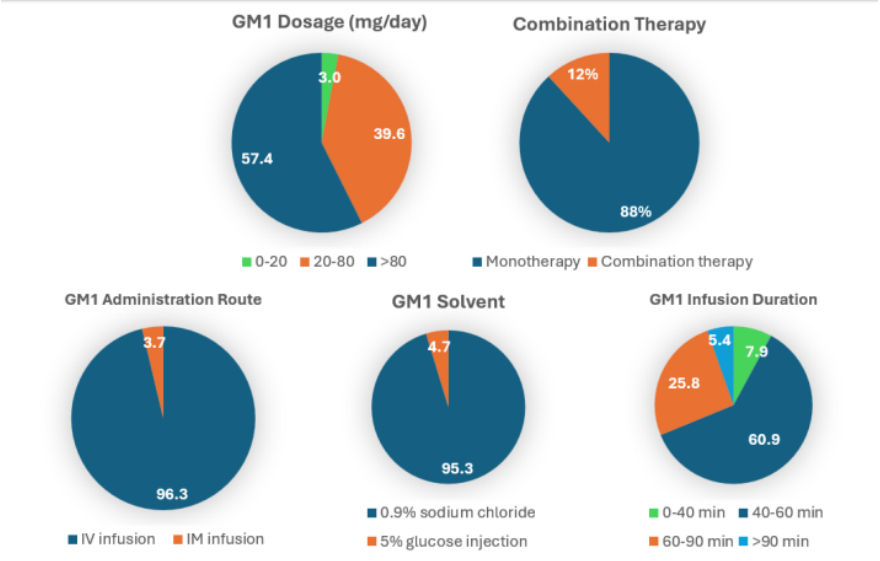


**Figure 2.** Patient medication information.

## 3.4. Information on adverse events of patients

Of the total 4405 participants, 1635 had adverse events, with an incidence rate of 37.1%. Digestive symptoms (such as bloating, abdominal pain, diarrhea, vomiting, decreased appetite, etc.) occurred in up to 70.9% of all adverse events. The vast majority (99.4%) of adverse events were mild, and no serious adverse events occurred. Of these, 244 patients (14.9%) had management measures for adverse events [5–7]. The results are shown in **Table 4** and **Figure 3**.

**Table 4.** Information table of adverse events of patients

| Name | |
|---|---|
| Total adverse events | |
| Yes | 1635 (37.1) |
| Not | 2777 (62.9) |
| Adverse reactions affect the system and symptoms | |
| Digestive system (such as bloating, abdominal pain, diarrhea, vomiting, decreased appetite, etc.). | 1160 (70.9) |
| Neurological system (e.g., transient speech disorders, confusion, lethargy, rare seizures, tinnitus, deafness, dizziness, etc.). | 310 (19.0) |
| respiratory system (respiratory distress, respiratory paralysis, shortness of breath, etc.). | 33 (2.0) |
| Systemic symptoms (profuse sweating, chills and tremors in the limbs, sore limbs, bruising of the lips and limbs, etc.). | 44 (2.7) |
| Eye diseases (such as blurred vision, pain in both eyes, swelling of the upper eyelids, conjunctival congestion, tearing, etc.). | 22 (1.3) |
| other | 66 (4.0) |
| Adverse event severity | |
| Mild | 1625 (99.4) |
| Moderate | 10 (0.6) |
| Severe | 0 (0.0) |
| Whether to take treatment measures | |
| Be | 244 (14.9) |
| Not | 1391 (85.1) |

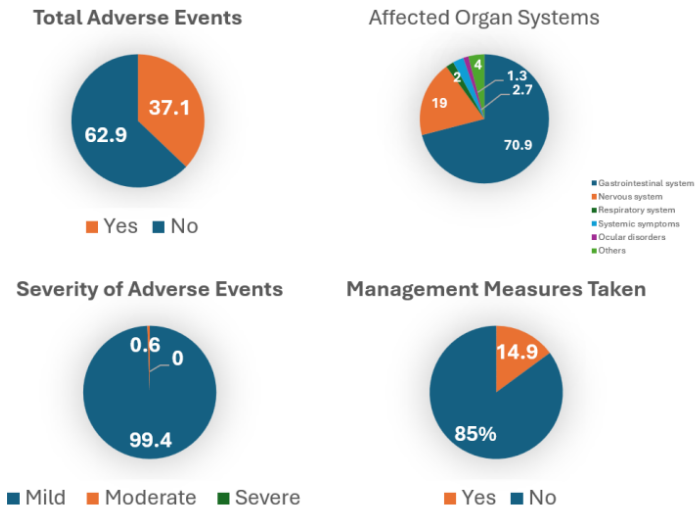


**Figure 3.** Infographic of patient adverse events.

### 3.5. Efficacy evaluation information

Before GM1 treatment, the mean NIHSS score of all patients was 14.0 points, and the mean NIHSS score after treatment was 10.1, with an average decrease of 3.9 points. Before GM1 treatment, there were 742 patients with Barthel scores below 20 points, 1575 cases with 20–40 points, 1667 cases with 40–60 points, and 421 cases with 60 points or more. A total of 741 cases had Barthel scores below 20 points, 935 cases with 20–40 points, 1056 cases with 40–60 points, and 1673 cases with more than 60 points after medication. The Wilcoxon test results showed statistical significance. The results are shown in **Table 5**.

**Table 5.** Patient efficacy evaluation table

| | Before medication | After medication | Statistics | *P*-value |
|---|---|---|---|---|
| NIHSS score (mean ± SD) | 14.0 ± 8.0 | 10.1 ± 8.6 | 37.974 | < 0.001 |
| Barthel Index | | | 1122162 | < 0.001 |
| 20 points or less | 742 (16.8) | 741 (16.8) | | |
| 20–40 | 1575 (35.8) | 935 (21.2) | | |
| 40–60 | 1667 (37.8) | 1056 (24.0) | | |
| 60 or more | 421 (9.6) | 1673 (38.0) | | |

## 4. Discussion

Stroke is a sudden cerebrovascular disease, and its urgency and severity have always been a major medical and health problem at home and abroad. With the change of modern lifestyle, the incidence of stroke is gradually getting younger, which has triggered scholars in the industry to rethink the treatment of this disease [8,9]. At present, the management of the disease is gradually changing from traditional treatment methods to individualized and personalized treatment, not only considering the patient's clinical symptoms, but also taking into account the patient's physique, economic situation and personal needs. Under the trend of individualized treatment, the application of GM1 has shown significant therapeutic effects and high safety.

Of the total 4405 patients in this study, only 1635 cases experienced adverse events, with an incidence rate of 37.1%. Among them, digestive system symptoms were the main ones, accounting for 70.9%; 19.0% of neurological symptoms and 2.7% of systemic symptoms, such as profuse sweating, chills, and trembling limbs, sore limbs, etc.; There are also a few respiratory symptoms, eye diseases, and other symptoms that occur. It is worth noting that 99.4% of the adverse events were only mild, and no patients had severe adverse events, which can be considered to be safe for GM1 in the treatment of stroke.

In terms of treatment effectiveness, the average NIHSS score of all patients before treatment with GM1 was 14.0 points, and the average NIHSS score after treatment was 10.1, with an average decrease of 3.9 points. The Barthel Index after treatment was statistically significant by Wilcoxon's test, and it can be considered that GM1 effectively improved the recovery of stroke patients and improved their daily living ability of stroke patients.

## 5. Conclusion

To sum up, GM1, as a highly safe brain-protective drug, can treat stroke well, and it has a significant effect

in promoting neurological function recovery and improving quality of life. In the face of the trend of younger stroke, individualized and personalized treatment strategies are particularly important. Future research should focus on how to optimize the treatment regimen of GM1 to improve its safety and therapeutic efficacy to better meet the treatment needs of different patients. At the same time, strengthening the study of GM1 mechanisms may provide a theoretical basis and technical support for the development of new therapeutic drugs.

## Disclosure statement

The authors declare no conflict of interest.

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