Efficacy of Butylphthalide Soft Capsules Combined with Shuxuetong Injection in the Treatment of Acute Cerebral Infarction

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【Abstract】Objective: To study the clinical effect of butylphthalide soft capsule combined with Shuxuetong injection in the treatment of acute cerebral infarction. Methods: A total of 94 patients with acute cerebral infarction admitted in our hospital from March 2018 to February 2020 were selected and divided into two groups according to the random number table method. The patients in both groups received conventional treatment programs, the control group (n=47) was given Shuxuetong injection, the test group (n=47) was given combination therapy of butylphthalide soft capsules and Shuxuetong injection on the basis of conventional treatment, and compared the efficacy and related indicators of patients in the two groups.

Results: The total effective rate of treatment in the test group was 95.74%, which was significantly higher than that in the control group, which was 80.85%; the NIHSS score in the test group was lower than that in the control group, and the ADL score was higher than that in the control group; the complication rate in the test group was 14.89%, which was significantly lower than the control group’s 40.43%, the difference between the two groups of data is statistically significant (P<0.05).

Conclusion: For patients with acute cerebral infarction, the use of butylphthalide soft capsules combined with Shuxuetong injection can achieve the desired results, and it has a positive effect on the recovery of nerve function and self-care ability, and it can also reduce the risk of complications. It is a treatment plan that is worth promoting.

1. Introduction:
Acute cerebral infarction is a cerebrovascular accidental disease with a rapid onset, rapid progress, and a very high mortality rate. It is mainly caused by various causes of blood supply disorders in the local brain tissue area, resulting in cerebral ischemia and hypoxic lesion necrosis, and cause nerve function damage[1]. The disease occurs in middle-aged and elderly people over 50--60 years old, and patients are likely to be accompanied by disorders of limb movement, difficulty swallowing, and aphasia after onset, which has a serious impact on their daily activities and quality of life[2]. Clinically, for the treatment of patients with acute cerebral infarction, restoring blood oxygen supply and nerve function of brain tissue is the key; In order to explore a more ideal treatment plan, our department treated 94 patients in groups to discuss the clinical efficacy of the butylphthalide soft capsule combined with Shuxuetong injection scheme. The research process and treatment results are now reported as follows:
2. Baseline data and methods

2.1 Baseline data
The patients with acute cerebral infarction who were treated in our hospital from March 2018 to February 2020 were included in the research team. The sample size was 94. Imaging examinations such as head CT and MRI after admission were all in line with the "China Acute Ischemic Diagnostic Criteria in Stroke Diagnosis and Treatment Guidelines 2014"[3]. (1) Inclusion criteria: meet the acute diagnostic criteria, the onset time does not exceed 72h, the coagulation mechanism is normal and there is no bleeding tendency, and there is no history of previous stroke. (2) Exclusion criteria: exclude those with malignant tumors, heart, lung, liver, and kidney dysfunction, systemic infectious diseases, and autoimmune diseases, and exclude those who have used hormones, immunosuppressants, and anti-inflammatory drugs within 4 weeks.

According to the random number table method, the patients were divided into two groups: the test group (n=47) was composed of 27 male and 20 female patients, with age distribution in the range of 46-75 years, with an average of (61.5±4.5) years; Comorbidities: 11 cases of hypertension, 12 cases of coronary heart disease, 6 cases of hyperlipidemia, 3 cases of diabetes. The control group (n=47) is composed of 28 males and 19 females, with ages ranging from 46 to 77 years, with an average of (62.3±4.8) years; comorbidities: 10 patients with hypertension and 11 cases with coronary heart disease, 7 cases of hyperlipidemia, 4 cases of diabetes. A statistical comparison of the data on the two groups of patients showed that P>0.05, which is comparable to the study.

The study has been reviewed by the ethics committee, and the patients and their families have the right to know about the study.

2.2 Method
All patients received conventional treatment after admission, including oxygen inhalation, anti-platelet aggregation, dehydration, improvement of micro-circulation, control of blood pressure, etc., and correction of water and electrolyte disorders to maintain acid-base balance. Lipid-lowering treatments should be given to those patients with basic diseases such as hypertension, diabetes, hyperlipidemia, active antihypertensive, hypoglycemic. All patients took aspirin enteric-coated tablets (Changchun Bethune Pharmaceutical Co., Ltd., National Pharmaceutical Standard H22022273), 0.1g per day, once a day.

Control group: patients were treated with Shuxuetong injection (Mudanjiang Youbo Pharmaceutical Co., Ltd., National Pharmaceutical Standard Z20010100) and 6ml injection was mixed with 250ml sodium chloride injection (0.9%) for intravenous drip, once a day with continuous medication for 14 days.

Test group: The usage and dosage of Shuxuetong are the same as those in the control group, and also treated with butylphthalide soft capsules (Shiyao Pharmaceutical Group Enbi Pharmaceutical Co., Ltd., Sinopharm H20050299), 2 capsules at a time, 3 times a day with continuous medication for 14 days.

After the course of treatment, the efficacy of the two groups of patients was compared.

2.3 Criteria for evaluating efficacy [4]
Before and after treatment, the NIHSS assessment scale was used to evaluate the degree of neurological deficits of the patients. The evaluation content included consciousness, language, visual field, facial paralysis, etc. The total score range was 0--24 points. A higher score indicates a more severe defect of neurological function. Count the reduction rate of NIHSS score by "(before treatment score - post treatment score)/before treatment score × 100%".

After treatment, if the patient's NIHSS score reduction rate is 90% or above, it is counted as level 0 disability and the treatment is basically cured; if the NIHSS score reduction rate is within the range of 46%-89%, it is counted as level 1--3 disability, and the treatment is markedly effective; if the NIHSS score reduction rate is within the range of 18%-46%, the treatment is effective; if the NIHSS score reduction rate is less than 18%, the treatment is ineffective.
The statistical value of the total effective rate of treatment = (number of basic cure cases + number of markedly effective cases + number of effective cases) / total number of cases × 100%.

2.4 Observation indicators
(1) NIHSS score.
(2) ADL score: Before and after treatment, the Barthel index scoring method was used to evaluate the patient's daily life ability. A higher ADL score indicates a better self-care ability \[^5\].
(3) Complication rate.

2.5 Statistical methods
The statistical software SPSS22.0 was used to analyze and test the research data. The comparison result of the measurement data (\(X \pm s\)) was verified by \(T\) value, and the comparison result of the count data (n, %) was verified by \(X^2\) values, when \(P<0.05\), it shows the inter-group comparison standards has significant differences.

3. Research results

3.1 Differences in total treatment efficiency between two groups
The total effective rate of treatment in the test group was 95.74%, which was significantly improved compared with 80.85% in the control group. The comparison between the groups was \(P<0.05\); see Figure 1.

| Group          | Cases | Basically cured | Marked effective | Effective | Ineffective | Total effective rate |
|----------------|-------|-----------------|------------------|-----------|-------------|----------------------|
| Test group     | 47    | 10              | 21               | 14        | 2           | 95.74% (45/47)       |
| Control group  | 47    | 5               | 16               | 17        | 9           | 80.85% (38/47)       |
| \(X^2\)        |       |                 |                  |           |             | 5.0449               |
| \(P\)          |       |                 |                  |           |             | 3.7065               |

Figure 1: Comparison of differences in total treatment efficiency between two groups (n, %)

3.2 Differences in NIHSS score and ADL score between two groups
Before treatment, there was no significant difference between the NIHSS score and ADL score of the two groups of patients, \(P>0.05\); after treatment, the two scores of the patients in the test group were better than the control group, and the data comparison between the groups was \(P<0.05\); see Figure 2.

| Group          | Cases | Before treatment | After treatment | Before treatment | After treatment |
|----------------|-------|-----------------|----------------|-----------------|----------------|
| Test group     | 47    | 14.02 ± 1.46    | 5.54 ± 0.85    | 45.12 ± 3.21    | 75.82 ± 3.89   |
| Control group  | 47    | 14.25 ± 1.50    | 9.40 ± 1.02    | 44.98 ± 3.05    | 62.35 ± 3.76   |
| \(t\)          |       | 0.7533          | 19.9307        | 0.2168          | 17.0690        |
| \(P\)          |       | 0.4532          | 0.0000         | 0.8289          | 0.0000         |

Figure 2: Differences in NIHSS score and ADL score between the two groups (\(X \pm s\), points)

3.3 Differences in the incidence of complications between the two groups
The incidence of complications in the test group decreased significantly compared with the control group, and the comparison data between the groups was \(P<0.05\); see Figure 3.
Group Cases Bleeding after infarction Hypoproteinemia Aspiration pneumonia Anxiety Complication rate
Test group 47 1 2 1 3 14.89% (7/47)
Control group 47 3 5 3 8 40.43% (19/47)
$\chi^2$ 7.6561
P 0.0057

Figure 3: Differences in the incidence of complications between the two groups (n, %)

4. Discussion
Acute cerebral infarction is more common in neurosurgery. It refers to a disease of brain tissue necrosis caused by a sudden interruption of blood supply to the brain. It can damage the brain nerves and cause dysfunction in its innervation area, such as hemiplegia and aphasia. The mechanism of ischemic necrosis of nerve cells is relatively complicated. In its occurrence and progression, it is closely related to various factors such as energy metabolism disorders, free radical damage, calcium overload, ischemic cerebral edema, cytokine changes, etc[6]; in the clinical treatment of patients, protecting brain cells and scavenging free radicals is the key to acute cerebral infarction. Our hospital advocates the combination of Shuxuetong injection and butylphthalide capsules on the basis of previous conventional treatments, of which Shuxuetong injection is a traditional Chinese medicine preparation with effect of blood circulation and dredging meridians and activating collaterals, and the main components are leeches, Dilong, etc. This drug can promote the absorption of acute cerebral hemorrhage, reduce brain tissue damage, which can effectively inhibit platelet aggregation and improve microcirculation[7]. Intravenous infusion for patients with acute cerebral infarction can promote the generation of human tissue-type plasminogen activator secreted by cerebral vascular endothelial cells, thereby accelerating thrombolysis. Butylphthalide capsule is an anti-cerebral ischemic drug that has selective inhibitory effect on arachidene and can inhibit various pathophysiological processes mediated by metabolites, and has a good effect on alleviating microvascular spasm and inhibiting platelet aggregation. The use of this drug for patients with acute cerebral infarction can inhibit the synthesis of TXA2 in cerebral cortical cells and promote the synthesis of PCI2, thereby alleviating cerebral vasospasm, restoring blood flow to the cerebral ischemic area, and reducing the area of cerebral infarction. In addition, butylphthalide soft capsules can also improve mitochondrial membrane potential, improve mitochondrial function, and gradually restore ATP levels and creatine phosphate levels in the brain, which helps to improve cerebral ischemic tolerance[8]. The combination of butylphthalide capsules and Shuxuetong in the treatment of acute cerebral infarction can effectively remove free radicals and improve brain metabolism, thereby restoring blood oxygen supply to brain tissue, protecting neurons, and improving nerve function. The results of this study showed that the total effective rate of treatment in the test group was higher than that in the control group. The NIHSS score, ADL score, and complication rate of the test group after treatment were significantly superior to those in the control group. The data comparison between the groups was P<0.05. This result also fully highlights the role and value of the combination of butylphthalide capsules and Shuxuetong.

In summary, the use of butylphthalide soft capsules combined with Shuxuetong injection in the treatment of acute cerebral infarction has an ideal effect and it helps to restore the daily life of patients, and can reduce complications. It is worth promoting.

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