# 都可喜治疗老年性痴呆36例临床观察

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**摘要：目的**　观察都可喜治疗脑萎缩所致老年性痴呆的临床疗效和不良反应。**方法**　采用随机开放平行对照观察49例，其中治疗组36例，口服都可喜片；对照组13例，口服脑复新片（盐酸吡硫醇）。**结果**　都可喜治疗组有效率为77.7%，而脑复新治疗组仅38.4%，两组比较 $P<0.05$，都可喜治疗组临床疗效明显优于对照组。**结论**　都可喜可作为治疗脑萎缩所致老年性痴呆的首选药物，对早期患者疗效更佳。

**关键词：**都可喜；老年性痴呆；疗效；不良反应

DUKEXI is a commercial name of Almitrine/Raubasine tablet including both consistents, which original function is used to treat the deficiency of intelligence capacity of elderly with the symptoms of sight and audible injuries original from blood vessel and the sequela of subacute cerebrovascular accident[1]. Pyitinol Hydrochloride is used to treat Alzheimer's disease[1], but the effect was said not ideal one. Many physicians have been hoping to have a new medicine to substitute it. According to the function of DUKEXI, it was hypothesis that DUKEXI could be helpful to treat this disease better than the other medicine. Therefore since 1998, we have tried to apply it to treat Alzheimer's disease due to the brain atrophy. In order to observe the effects of DUKEXI while treating this disease, we used the Pyitinol Hydrochloride as a control. This report is for the compared observation of treatment between two medicines.

## MATERIALS AND METHODS

General data: 49 patients were randomly divided into two groups, 36 cases with DUKEXI as a treatment group and 13 cases with Pyitinol Hydrochloride as a control group. The average ages of men and women (27 and 9 cases in treatment group, 13 and 8 cases in control group) were (63.4 ± 5) and (62.5 ± 6) years, respectively. There was no significant difference in educated level and occupation before their retirement.

Diagnosis criteria: The diagnosis criteria was used accordance with the one issued by the Health Ministry of P. R. China in 1995, which referred to DSM-III criteria from American psycho Committee in 1983[1]: That is, that the society activity is affected due to decreasing intelligence; One of the possible memory disorder, 1. the disturbance of abstract thinking: disability of proverb explanation that similar and different points of words can not be distinguished and words and concepts can not be defined; 2. disorder of judgment; 3. disorder of other higher cerebral cortex functions, such as, anepia, apraxia, agnosia and structure apraxia; 4. the change of personality, for example, change or reinforcement of original characteristics.

Case selection: The patients must be coincidence with the criterions above, and no original disease from lever hepar, kidney and hematopoietic system, as well as non-psycho. Also, the patients could took with the order from physician.

The method of therapy: With the method of parallel comparison, the patients in treatment group took DUKEXI tablets (including Almitrine 30 mg and Raubasine 10 mg per tablet), 1 tablet per time, 3 times per day, 30 days per therapy; and in control group Pyitinol Hydrochloride (o. 1 g per tablet), 2 tablets per time, 3 times per day, 30 days per therapy. 2 therapies were given in this study. All the patients would not take any pill for one week between 2 therapies.

The evaluated criteria of treatment effect and observation of efficiency: This criterion is taken from the Instructional Principle of clinical research in new Chinese traditional medicine issued the Health Ministry of P. R. China in 1995[2]. Inefficiency: Main symptoms with no change and continually worse. Efficiency: Parts of main symptoms are relieved, partly able to take care of shelf life and basically able to make correct answer, but response still slow. Obvious efficiency: Most of main symptoms have recovered to the normal, such as, better orientation and response than before, question answered become better.

Excellency: Main symptoms are basically controlled, such as, normal orientation, correct answer to the question and able to take part in general society activity.

The efficiency of general clinic and symptom improvement were evaluated. In order to inspect the consolidated efficiency after treatment, 46 cases (34 in treatment group and 12 in control group) were followed-up in 30 days after the medicine was halted. Also, the relationships among the general clinical efficiency in treatment group and age, sex and disorder duration were evaluated

Statistics: $\chi^2$ test was used for statistic analysis. The level of significance was set at $P<0.05$.

**RESULTS**

Clinical effect: After two therapies, the efficiency in treatment group was significantly higher than in the control group, $P<0.05$ (Table 1). The symptoms of patients in the treatment group was more significantly improved than in the control group, $P<0.01$ (Table 2). The consolidated efficiency also showed greater level in treatment group than in control group ($P<0.01$) (Table 3). All these

**Tab 1** The general clinical efficiency in two groups.

| | | Excellency | | Obviouse efficiency | | Efficiency | | Inefficiency | | General efficiency | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Group | $n$ | $n$ | % | $n$ | % | $n$ | % | $n$ | % | $n$ | % |
| Treatment | 36 | 17 | 47.2 | 6 | 16.6 | 5 | 13.8 | 8 | 22.2 | 28 | 77.7 |
| Control | 13 | 2 | 15.3 | 1 | 7.6 | 2 | 15.3 | 8 | 61.5 | 5 | 38.4 |

**Tab 2** The efficiency comparison of symptom improvement between two groups.

| Symptom | Efficiency | | | | $P$ |
|---|---|---|---|---|---|
| | Treatment group($n$=36) | | Control group ($n$=13) | | |
| | $n$ | % | $n$ | % | |
| Intellect decrement | 28 | 77.7 | 2 | 15.3 | <0.01 |
| Memory retention | 28 | 77.7 | 5 | 38.4 | <0.01 |
| Inability of abstract thinking | 21 | 58.3 | 5 | 38.4 | <0.01 |
| Disturbance in judgement | 28 | 77.7 | 3 | 23.0 | <0.01 |
| Personality change | 23 | 63.8 | 5 | 38.4 | <0.01 |

**Tab 3** The comparison of consolidated efficiency in 30 days after halted treatment between two groups.

| | | Excellency | | Obviouse efficiency | | Efficiency | | Inefficiency | | General efficiency | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Group | $n$ | $n$ | % | $n$ | % | $n$ | % | $n$ | % | $n$ | % |
| Treatment | 34 | 18 | 32.9 | 6 | 17.6 | 7 | 20.5 | 3 | 8.8 | 31 | 91.2 |
| Control | 12 | 0 | | 2 | 16.6 | 2 | 16.6 | 8 | 66.6 | 4 | 33.3 |

The relationships between the effect of DUKEXI with age, sex and suffering duration: There was no significant difference among the different group of ages and between sexes in the treatment group ($P>0.05$) (Table 4 and 5). They indicated that the action of DUKEXI for treating Alzheimer's disease was not affected by age and sex, respectively.

**Tab 4** The relationship between the clinical efficiency and ages.

| | | Obviouse | | | | | | | General | |
|---|---|---|---|---|---|---|---|---|---|---|

| Age (years) | n | Excellency n | % | Obviouse efficiency n | % | Efficiency n | % | Inefficiency n | % | General efficiency n | % |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 50～60 | 11 | 7 | 63.0 | 1 | 9.0 | 1 | 9.0 | 2 | 18.1 | 9 | 81.8 |
| 61～65 | 14 | 5 | 35.7 | 3 | 21.4 | 3 | 21.4 | 3 | 21.4 | 11 | 78.6 |
| 66～70 | 5 | 2 | 40.0 | 1 | 20.0 | | | 2 | 40.0 | 3 | 60.0 |
| 70～76 | 6 | 3 | 50.0 | 1 | 16.6 | 1 | 16.6 | 1 | 16.6 | 5 | 83.0 |

**Tab 5** The relationship between the clinical efficiency and sex.

| Sex | n | Excellency n | % | Obviouse efficiency n | % | Efficiency n | % | Inefficiency n | % | General efficiency n | % |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Male | 27 | 13 | 48.1 | 4 | 14.8 | 3 | 11.1 | 7 | 25.9 | 20 | 74.0 |
| Female | 9 | 4 | 44.4 | 2 | 22.2 | 2 | 22.2 | 1 | 11.1 | 8 | 88.8 |

However, there was significant difference among the groups of disorder duration, in which there was no significant difference between groups 1 and 2 ($P>0.05$) but there was significant difference between groups 2 and 3 ($P<0.01$) (Table 6). It indicated that the shorter the suffering duration, the better efficiency the clinical treatment of DUKEXI.

**Tab 6** The relationship between the clinical efficiency and suffering duration

| Groups | Disorder duration | n | Excellency n | % | Obviouse efficiency n | % | Efficiency n | % | Inefficiency n | % | General efficiency n | % |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | <1 | 20 | 15 | 75.0 | 3 | 15.0 | 1 | 5.0 | 1 | 5.0 | 19 | 95.0 |
| 2 | 1～4 | 9 | 2 | 22.2 | 2 | 22.2 | 3 | 33.3 | 2 | 22.2 | 7 | 77.8 |
| 3 | >4 | 7 | 0 | | 1 | 14.3 | 1 | 14.3 | 5 | 71.4 | 2 | 28.6 |

Safety observation: Before medications, all of the patients had to be asked to have their body examination, ECG, function of liver and kidney and the regular tests of their blood, urine and stool. However, there was no significant difference in these tests and examinations between two groups. After 30 days of taking these medications, there was no abnormal phenomenon observed in all of the patients except 4 cases, who had slight urine proteins and leucocytes before starting medications. Then 2 cases had recovered to the normal after 30 days of treatment. After finishing 2 therapies, all these above mentioned would check again. Also, no abnormal change could be found.

Side-effect of DUKEXI: 11 of 36 cases of patients in the treatment group of DUKEXI had some side effects (see Table 7), but we did not do any treatment for them except the hard stool in some patients who were given some medicines for easy relieving. There was no significance of side effect between two groups (Table 7).

**Tab 7** The comparison of side-effect incidences between two groups

| Group | n | Agrypnia n | % | Anxiety n | % | Nausea n | % | Decreased food appetite n | % | Hard stool n | % | Cutaneous eruption n | % |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Treatment | 36 | 4 | 11.1 | 3 | 8.3 | | | 2 | 5.6 | 2 | 5.6 | 11 | 30.56 |
| Control | 13 | 2 | 15.4 | | | 3 | 12.8 | 2 | 15.4 | 1 | 7.6 | 8 | 61.53 |

**Discussion**

Brain atrophy causes Alzheimer's disease. There are 48-65% of Alzheimer's diseases, which results from original regression of central nerve system. The clinical characteristics manifest the losses of memory and abstract thinking, the changes of personality and behavior. The CT image of brain shows a widespread atrophy of brain cortices.

48 cases of patients in this study had the atrophy of brain cortices in the CT images. DUKEXI can improve the blood circulation of whole brain so as to increase PaO2 in artery blood, decrease the desaturation of artery blood oxygen during movement, elevate the level of 2,3 diphosphoric glycerol acidic salt in blood[3]. Therefore, it can be apply for improving the above symptom of Alzheimer's disease induced due to the original regression of central nerve system.

Nowadays, Pyitinol Hydrochloride is used to treat Alzheimer's disease induced due to the atrophy of brain cortices. In order to test the effect of DUKEXI treatment to

Alzheimer's disease induced due to the atrophy of brain cortices, we applied Pyitinol Hydrochloride as a control reference for the paralleled comparison. After two therapies, the efficiency of DUKEXI was 77.7% and of Pyitinol Hydrochloride was only 38.4%, which manifested that the action of DUKEXI for treating Alzheimer's disease induced due to the atrophy of brain cortices was more excellent than Pyitinol Hydrochloride. Following up after 30 days of halting therapy, the consolidated efficiency of main symptoms in DUKEXI group was 91.2%, and the symptoms of some patients obtained very obvious improvements.

There was no direct relationship between the clinical efficiency of DUKEXI and age and sex of patients, but there was an intimate relationship in the suffering duration. The significant difference of treatment efficiency was great between the groups of suffering duration $<1$ year and $>4$ years. It may indicate that the earlier applying this medicine, the better the effect. The safety observation in the treatment group showed that DUKEXI was no specific side effect, except 11 cases of patients (30.7%) with some side effects which was indicated in the introduction of DUKEXI.

As a result, it was considered that DUKEXI should be an ideal medicine for treating Alzheimer's disease induced due to the atrophy of brain cortices.

**REFERENCE**


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