Evaluation by Survival Analysis on Effect of Traditional Chinese Medicine in Treating Children with Respiratory Syncytial Viral Pneumonia of Phlegm-Heat Blocking Fei Syndrome*

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ABSTRACT Objective: To objectively evaluate the clinical effect of traditional Chinese medicine in treating children’s respiratory syncytial viral pneumonia (RSVP) of phlegm-heat blocking Fei (肺) syndrome (PHBFS).

Methods: A single-blinded multi-center, blocked, randomized and parallel-controlled method was adopted. The clinical study was carried out on 206 children with RSVP-PHBFS who were assigned to two groups, 108 in the test group treated through intravenous dripping of Qingkailing Injection (清开灵注射液) in combination of oral intake of ribavirin injection in combination with oral intake of potassium guaiacol sulfonate oral liquid, all for 10 days. The clinical efficacy was evaluated and compared at the end of the trial from various aspects by three methods including comprehensive efficacy, post-treatment main symptoms score difference and survival analysis of the two groups in the effect initiating time on such symptoms as fever, cough, copious sputum, shortness of breath, and rales, which was earlier in the test group (P=0.0348). Scores of the main symptoms were lowered after treatment in both groups, the difference was 22.41 ± 4.99 scores in the test group and 17.61 ± 6.34 scores in the control group, being more significant in the former (t=−5.99, P<0.01). Survival analysis shows that there was significant difference between the two groups in the effect initiating time on such symptoms as fever, cough, copious sputum, shortness of breath, and rales, which was earlier in the test group (P<0.01 or P<0.05). Conclusion: Evaluation of the efficacy of traditional Chinese medicine in treating children with RSVP-PHBFS by using the three methods jointly could better show the objectivity of the evaluation.

KEY WORDS children respiratory syncytial viral pneumonia, phlegm-heat blocking Fei syndrome, therapeutic effect evaluation, survival analysis

Respiratory syncytial viral pneumonia (RSVP) is a commonly encountered disease in pediatric clinics. In the period from January 2005 to February 2007, adopting a multi-center, blocked, randomized and parallel-controlled principle of trial, a study on the effectiveness of traditional Chinese medicine (TCM) on 206 RSVP patients of phlegm-heat blocking Fei syndrome (PHBFS) was conducted by the special research group composed of the Affiliated Hospital of the Nanjing University of Traditional Chinese Medicine, the Beijing Children’s Hospital Affiliated to the Capital Medical University, First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine, First Subsidiary Hospital of Henan College of Traditional Chinese Medicine and Guangdong Provincial Traditional Chinese Medicine Hospital. The results are reported as follows.

METHODS

Standard for Diagnosis, Inclusion and Exclusion

Western medical diagnosis of RSVP was made according to the "Scheme for children’s pneumonia prevention and treatment" in the "Scheme for prevention and treatment of children’s four diseases" promulgated by the Ministry of Health, PRC⁷, and to the diagnostic standard of viral pneumonia set in the...
The subjects enrolled were inpatients matching the above-mentioned standards with ages between 3 months to 3 years with the course of pneumonia within 48 h. Laboratory examination shows WBC counts in normal range or slightly increased but equal to or below $12 \times 10^9/L$. Etiological immunofluorescent examination shows positive respiratory syncytial virus (RSV) in nasopharyngeal secretion.

Patients in the following conditions were excluded: premature infants or preemies; those at the time of enrolment complicated with heart failure, respiratory failure, toxic encephalopathy and exudative pleurisy; complicated with bacterial infection which made antibiotics necessary; complicated with serious primary diseases of heart, liver, kidney or hematopoietic system, or mental diseases; with other diseases or in conditions that were considered to have an influence on the probability or complexity of enrolling.

General Materials
Subjects were randomized into the test group and the control group in the ratio of 1:1, the difference between two groups was statistically insignificant in terms of sex, body weight, initiation of disease, course of pneumonia, as well as the baseline of life signs as body temperature, resting heart rate (HR) and breathing ($P>0.05$, Tables 1-3). Comparison between the two groups show no significant difference in aspects of dominant symptoms (fever, copious sputum, short breath, rales and chest X-ray figure), secondary symptoms (aversion to cold, cyanosis, nausea, vomiting,hidrosis and dry mouth), results of laboratory examinations (blood oxygen saturation and level of lymphocyte subsets), as well as HR, complexion, spirit, appetite, food taking, tongue figure, etc. ($P>0.05$), except the distribution of different baseline condition ($P=0.0405$), which was more severe in the test group than in the control group.

### Treatment
To the test group, Qingkailing Injection (清开灵注射液), a Chinese herbal medicine consisting of buffalo horn, scutellaria root, honeysuckle flower and cape-jasmine fruit, prepared by the Pharmaceutical Plant of the Beijing University of Chinese Medicine (batch number 612203A), was administered once a day at the dose of 10 mL for children aged 3 months to 1 year, and 15 mL for those over 1 year, via intravenous dripping with the medicine added into 10% glucose solution. Meanwhile, the Er’tong Qingfei Oral Liquid (儿童清肺口服液), a product of Tongrentang Pharmaceutic Factory, batch number 4260114-2, consisting of ephedra herb, apricot seed, gypsum fibrosum, mulberry bark, snakegourd peel, scutellaria root, isatis root, Zhejiang fritillary bulb, etc., was given to the control group, according to the instructions.