The risk in patients with pulmonary incompetence (PI) undergoing thoracic operations is much higher than that in patients with normal lung function. The over excision of lung tissue and the operational injury could impair a patient's lung function severely and cause serious complications or even death; the crippled lung function would lead to lowering of the patients' life activity. On the other hand, the over conservative therapy could engender losing the chance of cure in some patients. Because the receptibility to thoracic surgery tends to increase in patients with PI along with the progress of surgical technique and intensive care, the issue of how to improve surgical tolerability and post-operation rehabilitation in patients with PI has become indispensable. For this reason, the authors observed the effect of the Chinese medicine (CM), Yiqi Bufei Recipe (益气补肺方, YBR), on the changings of pulmonary and cardiac functions before and after operation in patients with PI after pneumonectomy. The study is reported as follows.

METHODS

Inclusion and Exclusion Criteria

Inclusion criteria: (1) patients with a diagnoses of bronchiectasis, lung carcinoma, bulla, damaged lung, etc., meeting the standards listed in the book "Thoracic and Cardiac Surgery"; (2) with any two items of lung function maximal ventilator volume per minute (MVV), forced vital capacity (FVC), and the first min forced expiratory volume (FEV1) <60% (regarded as PI); (3) matched to the CM diagnosis of Fei (肺) qi-yin deficiency syndrome; (4) showing no sign of respiratory or cardiac failure; (5) any sex, aged within 16–80 years; (6) participating in the study of their own will and who had signed an informing consent form.

Exclusion criteria: (1) with any two items of lung function (MVV, FVC, FEV1) <30%; (2) intolerant of the operation due to severe primary diseases of the
heart, liver, kidney, hematopoietic and endocrinal system, etc.; (3) with incurable respiratory failure, with PaO₂<60 mm Hg and PaCO₂>50 mm Hg; (4) with contra-indications to the operation as well as pregnant women; (5) incapable of cooperation due to mental disorder or nerve diseases, or unwilling to cooperate; (6) aged below 16 years or over 80 years; (7) concurrently taking other Chinese herbal medicines; (8) with severe hypertension.

Case Selection
All the 120 selected patients were in-patients with PI and were scheduled to receive pneumonectomy in the Hangzhou Hospital of Traditional Chinese Medicine and Zhejiang Provincial Hospital of Oncology from April 2006 to September 2010. Using a random number table, they were randomized into two equal groups: the test group and the positive control group. In addition, 60 patients with normal lung function who received operation were selected and set as the negative control group.

General Materials
The 60 patients in the test group included 39 males and 21 females, with an average age of 62.43 ± 10.58 years; the diagnoses were lung carcinoma in 39 patients, pulmonary tuberculosis in 7, bronchiectasis in 5, pneumonic pseudoplasm in 3, and other benign diseases in 6. The 60 patients in the positive control group included 35 males and 25 females, with an average age of 58.17 ± 9.90 years; the diagnoses were lung carcinoma in 37 patients, pulmonary tuberculosis in 4, bronchiectasis in 7, pneumonic pseudoplasm in 4 and other benign diseases in 8. The three groups were not statistically different in terms of sex, age, illness course, and diagnosis. The 60 patients in the negative control group included 41 males and 19 females, with an average age of 57.25 ± 10.54 years; the diagnoses were lung carcinoma in 33 patients, pulmonary tuberculosis in 8, bronchiectasis in 7, pneumonic pseudoplasm in 5 and other benign diseases in 7.

Treatment
According to the pre-operation appraisal, various kinds of pneumonectomies were performed on the patients. In the test group, 48 patients received pulmonary lobectomy, 8 received total pneumonectomy, 4 received segmental or cuneiform resection. The corresponding number of patients in the positive control group receiving the three kinds of operation were 43, 7, and 10, respectively, while those in the negative control group were 46, 6, and 8, respectively. After operation, all patients were treated with an effective auxiliary expectorant, anti-infectious/inflammatory approaches, and routine peri-operation treatment such as strengthening nutrition and appropriate functional exercise.

Additionally, to the patients in the test group, starting from the next day of operation, the YBR, composed of Radix Astragali 30 g, Radix Angelicae sinensis 6 g, Radix Ginseng 6 g, Radix Asparagi 6 g, Fructus Schisandrae 3 g and Radix Glycyrrhizae 3 g (all crude drugs were purchased from the Chinese Herbod Medicine Factory, Zhejiang University of Traditional Chinese Medicine), was given orally at one dose every day through a decoction of 200 mL, with the patient taking 100 mL twice a day for 7–14 days (average 10.6 ± 3.6 days).

Items of Observation
Post-operative hospitalizing days (HD) and intensive care unit (ICU) confinement time (ICUT) were observed. Mortality and incidence of post-operative complications, including: (1) common complications like hypoxemia, pulmonary infection, arrhythmia, broncho-pleural fistula, pulmonary embolism, etc.; (2) severe complications, such as respiratory and cardiac failure. Lung function and cardiac function examinations were determined before and 20 days after operation, using the Masterscreen Diffusion computerized pulmonary function analyzer (Jaeger, Germany) for detecting MVV, FVC, and FEV1, ABL5 automatic blood gas analyser (Radiometer, Denmark) was used for PaCO₂ and SaO₂ determination, while a colored Doppler’s ultrasonic diagnostic scanner (General Electric Company, England) was used to determine the ejection fraction (EF). Items for observation of safety included the conventional tests of blood, urine and stool, as well as the functional tests of the liver and kidney.

Statistical Analysis
SPSS 17.0 software was adopted. The measurement data were expressed as mean ± standard deviation; inter-group or pre-/post-treatment comparisons were analyzed by the paired t-test, the comparison of rates by the non-parametric Chi-square