Evaluation of the Clinical Efficacy of Qingqiao Capsule in Treating Patients with Secretory Otitis Media

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ABSTRACT
Objective: To observe the clinical efficacy of Qingqiao Capsule (QQC) in treating patients with secretory otitis media (SOM). Methods: A total of 90 patients were randomly assigned into the treated group (n=45) and the control group (n=45). Patients in the treated group were administrated with QQC, 5 capsules each time, 3 times a day for totally 10-14 days, and those in the control group were given per os cefaclor capsules 0.5g each time for adult, 3 times a day, or 20mg/(kg·d) for children, for 10-14 days. The therapeutic efficacy of treatment on the patients was observed and compared after treatment and followed up for 3-6 months. Results: (1) The clinical efficacy in the treated group was superior to that in the control group with significant statistical difference (P<0.01); (2) Comparison of the efficacies in patients of three different TCM syndrome types showed no statistically significant difference (P>0.05); (3) The vanishing rate and time needed of the main symptoms and signs in the treated group were superior to those in the control group on ear muffle, tinnitus, hearing impairment, hydrotypanum, pure tone threshold and abnormal tongue figure, and the difference was statistically significant (P<0.05 or P<0.01), only those of earache, otitis plexus and abnormal pulse figure were insignificantly different between the two groups (P>0.05). Conclusion: QQC is an effective Chinese composite medicine on patients with SOM, and shows no obvious adverse reaction.

KEY WORDS Qingqiao Capsule, secretory otitis media, integrated traditional Chinese and Western medical treatment, randomized controlled trial

Secretory otitis media (SOM), also called non-suppurative otitis media and glue ear, etc., is a frequently encountered disease in the middle ear in clinics. Especially in children of 2-7 years old, the incidence reached 7.3% to 30.7% (1). However, it would decrease along the increase of age. It is characterized by retention of exudative fluid in the middle ear but shows no acute infectious manifestation. A long-lasting SOM often causes hearing impairment. If untreated or improperly treated, it may be protracted and develop to adhesive otitis, tympanosclerosis, cochlear window impairment, or even inconvertible sensorineural deafness. The etiological factor and pathogeneses of SOM are not clear yet, so no effective medicine has been developed so far. Although Western drugs and local treatment have been extensively applied, their efficacy is still doubtful. In this study Qingqiao Capsule (QQC) and cefaclor capsule (CC) were used to treat SOM in a randomized controlled trial carried out from Jan. to Nov., 2004, and the results are now reported as follows.

METHODS

Diagnostic Criteria
By Western medicine (WM), the diagnostic criteria of SOM were defined on the basis of pertinent criteria published in the teaching material compiled by TIAN Yong-quan (2), which were: (1) having symptoms as earache, ear muffle, tinnitus and hearing impairment; (2) having signs of...
otoptosis, limited motion of tympanic membrane and hydrotympanum; (3) pure tone test prompting conduction deafness or mixed deafness; (4) acoustic immittance showing typical manifestation of flat type (type B), or high suction pressure type (type C) tympanogram, suggesting auditory tube dysfunction; and hydrotympanum with disappearance of stapedius reflex revealed in part of the patients; (5) exudative fluid aspirated by auripuncture.

By traditional Chinese medicine (TCM), the diagnostic criteria for SOM were set down in reference to the “National standard of PRC”, section of “Clinical terminology of diagnosis and treatment on TCM” and the relevant materials picked-up from the teaching material compiled by WANG Shi-zheng. Ear bulge was defined as an illness caused by exogenous evil invading into external acoustic meatus to block meridian Qi, mainly manifested as unwell fullness sensation or mild pain in ear, wind-like tinnitus, hearing impairment and enhanced self-hearing hallucination. Ear occlusion is mainly manifested by obstructive feeling and fullness sensation in the ear, which is protracted for a long time with gradually developing hearing impairment and noisy tinnitus.

By TCM syndrome differentiation, patients of SOM can be classified into three syndrome types, the type of auditory orifice stuffed up by external pathogenic wind invasion (Type I), the type of auditory orifice steamed up by Gan-Dan damp-heat (Type II) and the type of the ear blocked up by Pi-deficiency dysfunction induced dirty dampness (Type III).

All the patients with their conditions meeting the above criteria, their age ranging between 2—70 years and of either sex were enrolled in this study. And excluded were those who suffered from SOM caused by nasopharyngeal carcinoma or cleft palate, or from mechanical obstruction of auditory tube due to adhesive otitis or adenoid hypertrophy, or accompanied with serious rhinitis or sinusitis, nasal polyp or women in time of pregnancy or lactation as well as patients of psychiatric disease, liver or kidney functional disturbance, hemorrheological disease, and aero-otitis media, etc.

General Materials
The ninety cases were out-patients of the Sixth People’s Hospital of Zigong and the Second Affiliated Hospital of Luzhou Medical College, Sichuan Province, who were equally randomized into the treated group and the control group according to random number table. The 45 patients in the treated group were 23 males and 22 females, their age ranging from 5.9 to 68 years with mean age of 34.4 ± 14.6 years; course of disease ranging from 1 to 7 days in 14 patients, 8 to 30 days in 12, 31 to 180 days in 15, and 181 to 730 days in 4. The 45 patients in the control group were 26 males and 19 females, age ranging from 4 to 64 years with mean age of 27.9 ± 17.0 years; course of disease ranging from 1 to 7 days in 9 patients, 8 to 30 days in 9, 31 to 180 days in 19 and 181 to 750 days in 8.

Of all the patients, 53 patients had their age ranging between 4 to 28 years, accounting for 58.9%.

There was no statistical difference in terms of age, sex, course of SOM, pathogenetic factors, fundamental diseases, TCM syndrome types, degree of disease and patient’s quality of life as assessed by both the doctor and the patients themselves between the two groups (P > 0.05), and so they were comparable.

Treatment
The clinical trial was conducted adopting double-blinded method with QQC and CC. QQC is composed of 12 kinds of Chinese herbs, including Radix Scrophulariae, Radix Rehmanniae, Radix Salviae Miltiorrhizae, Radix Achyranthis Bidentatae, Bombyx Batryticatus, Radix Angelicae sinensis, Semen Coicis, Amomum kravanh Pirre ex Gagnep, Amomum kravanh Pirre ex Gagnep, Radix Glycyrrhizae, etc, each capsule weighing 0.45g, containing 2.25 g of crude drug, and the batch number was 20040426 and 20041028. Cefaclor capsule was product of Kunming Jida Medicine Co. Ltd., batch number 040301. The two test drugs were made up into a unified form by the Preparation Department of the Second Affiliated Hospital, Luzhou Medical College.

QQC was given to the patients in the treated group, 5 capsules every time, 3 times a day, taken per os with warm water, and the dose was reduced properly for children. CC was given to those in the control group, 0.5g each time for adults three times a day or 20 mg/(kg·d) for children, taken per os in three portions.

All the patients were treated for 10—14 days in total. No other drugs were given in the observation period. For patients who had obvious reten-