EVALUATION OF THERAPEUTIC EFFECTS OF "TAM AO THANG" IN ACUTE RHINOPHARYNGITIS IN PEDIATRIC PATIENTS

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Abstract

The study aimed to evaluate the therapeutic effects of "Tam ao thang" in the treatment of acute rhinopharyngitis in pediatric patients aged 2 to 5 years old. The results indicated that after 7 days of treatment, the overall efficacy in the treatment group was 86.7%, significantly higher than the 66.7% observed in the control group. The resolution of nasal mucosal congestion and the presence of mucus in the nasal floor was achieved in 90% of the treatment group, compared to 66.7% in the control group. Furthermore, the resolution of symptoms such as redness, swollen, and increased secretions of the pharyngeal mucosa was observed in 93.3% of the treatment group, compared to 70% in the control group. The rate of side effects such as vomiting and nausea after taking the medicine were low at 6.67% and no abnormal changes were found in hematological and biochemical tests before and after treatment.

Keywords: *Acute rhinopharyngitis, Tam ao thang, pediatric patients*

I. INTRODUCTION

Acute rhinopharyngitis is the acute inflammation of the mucous membrane in the nasopharyngeal area. This condition is common in young pediatric patients aged 2 to 5 years, with an average occurrence of 6-8 times per year compared to 4 times per year in older pediatric patients. The disease is often prevalent during the cold season in areas with fluctuating climates, peaking in autumn and winter or during sudden weather changes. It is primarily caused by viruses, accounting for 80% of cases. Although the disease is generally not dangerous, it presents several uncomfortable symptoms for pediatric patients, such as cough, phlegm, nasal congestion, runny nose, leading to fatigue, irritability, decreased appetite, and weight loss. The recurrent nature of the disease throughout the year not only diminishes the quality of life for pediatric patients but also impacts the care provided by parents and families [1],[2],[3].

Modern medicine primarily treats acute rhinopharyngitis caused by viruses symptomatically with antipyretics, anti-inflammatories, analgesics, cough suppressants, expectorants, nasal decongestants, and nasal hygiene [3]. However, in young pediatric patients, the use of chemical-based medications may

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lead to undesirable effects, such as nausea, vomiting, dizziness, hallucinations, and particularly respiratory depression when overdosed with cough suppressants like dextromethorphan and codeine [4].

In traditional medicine, acute rhinopharyngitis in pediatric patients is classified under the syndrome of "cough and phlegm" [5]. "Tam ao thang" is an ancient remedy originating from the "Thai binh hue dan hoa te cuc phuong"[6], consisting of the following ingredients: Ma Hoang (*Herbal Ephedra*), Hanh nhan (Semen Armeniacae), and Cam thao (Radix Glycyrrhiza), which have the effects of relieving cough, dispersing cold, soothing the throat, and calming asthma. This remedy has been applied clinically to support the treatment of acute rhinopharyngitis in pediatric patients with certain effectiveness, though it has not yet been scientifically studied and evaluated. While administering traditional decoctions to pediatric patients may not be convenient, this study aims to explore initial research for future adaptations of the formula suitable for pediatric patients. With the desire to combine modern medicine and traditional medicine to enrich the treatment methods for acute rhinopharyngitis in pediatric patient, the research group conducted the study titled "*Evaluation of the therapeutic effects of "Tam ao thang" in acute rhinopharyngitis in pediatric patients*" with the following objectives:

1. Evaluation of the therapeutic effects of "Tam ao thang" in treating acute rhinopharyngitis in children aged 2 to 5 years.

2. Investigation of the side effects of "Tam ao thang" when used in children aged 2 to 5 years.

II. METHODS

2.1. Material

The "Tam ao thang" formula includes [7]:

Ma hoang (*Herbal Ephedra*) 4g

Hanh nhan (*Semen Armeniacae*) 9g

Cam thao (*Radix Glycyrrhiza*) 4g

Dosage estimation for pediatric patients is calculated using the formula:

Estimated dosage = (S × Adult dosage)/1.75

S= (4P+7) / (P+90)

In which

- S: Body surface area (m^2)
- P: Weight (kg)
- Adult dosage: 300ml/day [4].

Dosage for pediatric patients:

Age	Ideal weight (kg)	Body surface area (m^2)	Percentage of adult dosage
2 years	12	0.54	31
3 years	14	0.61	35
4 years	16	0.67	38
5 years	18	0.73	42

Thus, the estimated dosage for pediatric patients is as follows:

- Ages 2-3: 100 ml/day
- Ages 4-5: 150 ml/day

Method of administration: Take twice daily, morning and afternoon, after meals.

2.2. Subjects

Pediatric patients aged 2-5 years diagnosed with acute rhinopharyngitis caused by viruses and treated at the Central Traditional Medicine Hospital, meeting the following criteria:

2.2.1. Inclusion criteria

According to Modern medicine: Diagnosis of acute rhinopharyngitis caused by viruses based on the "Guidelines for the diagnosis and treatment of some ear, nose, and throat diseases" by the Ministry of Health in 2016 [3]:

- General symptoms: Mild fever (38ºC-39ºC), occasionally high fever (40ºC) in pediatric patients, irritability, headache, fatigue.

- Functional symptoms: common symptoms include nasal congestion and a runny nose, with initially clear, mucoid discharge that later becomes cloudy. An irritating cough is also common, initially presenting as a dry cough and later as a productive cough with phlegm. The voice may become less clear or slightly hoarse, accompanied by a sore throat.

- Physical symptoms: The pharyngeal mucosa is red, swollen, and secreting. The nasal mucosa shows signs of congestion, swelling, and clear mucus discharge.

- Blood tests: White blood cell count is either normal or decreased, with possible lymphocyte levels exceeding 48%, and a normal neutrophil count ranging between 40% and 70%

- *According to Traditional medicine:*

- Diagnosis of "Cough and Phlegm" syndrome with Wind-cold type [5].

2.2.2. Exclusion criteria

- Non-compliance with treatment: missing medication for over 24 hours or parents giving antibiotics without a doctor's prescription.

- Rhinopharyngitis caused by bacterial infections or specific viruses (measles, dengue fever, etc.).

- Complications: cellulitis, peritonsillar abscess, abscess of the posterior or lateral pharyngeal wall, necrotizing cellulitis in the throat region, acute otitis media, bronchitis, pneumonia.

- History of chronic diseases; liver, kidney, heart failure, etc.

- Allergies to the ingredients in the studied formula or other base medications.

2.3. Methods

Study Design: Clinical intervention study with a controlled comparison before and after treatment, compared to a control group.

Sample Size: The minimum sample size was determined, and a convenient, purposive sampling method was used, including 60 pediatric patients meeting eligibility criteria. These patients were matched for similarity and divided into two groups: the study group and the control group, with 30 patients in each group.

Monitoring and Evaluation Indicators: At time points Day 0 (D0), Day 3 (D3), and Day 7 (D7).

- Evaluation of treatment outcomes based on symptom improvement after treatment: fever, nasal congestion, runny nose, sore throat, cough, phlegm, and nasopharyngeal mucosa.

- Evaluation of clinical side effects and blood test (including blood count, urea, creatinine, AST, ALT) was conducted before and after treatment.

- Scoring for each symptom [8]

Evaluation Treatment outcomes	**Score**
Resolved symptoms	0
Reduced but not completely resolved	1
No improvement	2

Overall scoring: Total score = (Score from nasal mucosa symptoms + Score from throat mucosa symptoms + Fever) × 3 + (Score from cough + phlegm) × 2 + (Score from sore throat + nasal congestion, runny nose) × 1.

- Good: Total symptom score ≤ 25% of total symptom score at D0.

- Fair: Total symptom score 25 - 50% of total symptom score at D0.

- Average: Total symptom score 50-75% of total symptom score at D0.

- Poor: Total symptom score < 75% of total symptom score at D0.

- Research process

- Research group: 30 pediatric

patients treated with the baseline regimen combined with the "Tam ao thang" formula.

- Control group: 30 pediatric patients treated with the baseline regimen.

- Baseline regimen in the study includes:

- Paracetamol 150mg used when temperature ≥ 38.5ºC, dosage 10-15mg/kg/dose every 4-6 hours.

- Nasal drops: Otrivin 0.05%, 1-2 drops in each nostril, 1-2 times/day after nasal cleansing with 0.9% NaCl saline solution.

- Nasal drops: 0.9% NaCl, 3-4 times/day.

2.4. Data processing and Analysis methods

The collected data were processed using biostatistical algorithms with SPSS 20.0 software. Mean values $\overline{X}$ and standard deviations (SD) were calculated, and group means were compared using the T-test, while group proportions were compared using the χ^2 test. Statistical significance was considered at $p < 0.05$.

2.5. Research location and duration

The study was conducted in the Pediatrics and Otolaryngology departments of the National Hospital of Traditional Medicine from September 2017 to August 2018.

2.6. Ethical considerations in research

- The study was approved under Decision No. 4995/QĐ-ĐHYHN by Hanoi Medical University and received the consent of the National Hospital of Traditional Medicine.

- Only pediatric patients whose parents or guardians consented, after being informed of the study's purpose and requirements, voluntarily agreed to participate were included.

- All personal information of the pediatric patients was kept confidential.

- Collected data were used solely for research purposes to improve treatment quality, with no other intended usage.

III. RESULTS

3.1. The therapeutic effects of "Tam ao thang" in treating acute rhinopharyngitis in children aged 2 to 5 years

Table 1. Clinical Characteristics before Treatment

Group / Symptoms	Research Group (n=30)		Control Group (n=30)		p
	n	Percentage (%)	n	Percentage (%)	
Fever	30	100	30	100	
Cough	25	83.3	26	86.7	> 0.05
Phlegm	24	80	24	80	> 0.05
Sore throat	23	76.7	22	73.3	> 0.05
Nasal congestion, runny nose	25	83.3	26	86.7	> 0.05
Nasal mucosa congestion, nasal floor with clear mucus	30	100	30	100	
Throat mucosa reddened, swollen, increased secretion	30	100	29	96.7	> 0.05

Comment: The symptoms of fever, nasal mucosa congestion, nasal floor with clear mucus, and throat mucosa being reddened, swollen, and increased secretion accounted for the highest rates of 96.7% - 100%. Symptoms of nasal congestion, runny nose, cough, and phlegm were lower, at 80% - 86.7%. The symptom of sore throat had the lowest rate. There were no differences in the rates of symptoms between the two groups with $p > 0.05$.

Table 2. The rate of children who resolved symptoms of congested nasal mucosa with clear mucus discharge at various treatment time points

Group / Time point	Research Group (n=30)		Control Group (n=30)		p
	n	Percentage (%)	n	Percentage (%)	
D0	0	0	0	0	
D3	12	40	8	26.7	> 0.05
D7	27	90	20	66.7	< 0.05
p (D0 - D3)					
p (D3 - D7)	< 0.05		< 0.05		
p (D0 - D7)					

Comment: The rate of pediatric patients free from symptoms of nasal mucosa congestion and nasal floor with clear mucus increased over the treatment period in both groups. After 7 days of treatment, the rate of pediatric patients free from symptoms in the research group (90%) was higher than in the control group (66.7%). The difference was statistically significant with $p < 0.05$.

Table 3. The rate of children who resolved symptoms of red, swollen throat mucosa with increased discharge at various treatment time points

Group / Time point	Research Group (n=30)		Control Group (n=30)		p
	n	Percentage (%)	n	Percentage (%)	
D0	0	0	1	3.33	> 0.05
D3	13	43.3	9	30	> 0.05
D7	28	93.3	21	70	< 0.05
p (D0 - D3)			< 0.05		
p (D3 - D7)	< 0.05		< 0.05		
p (D0 - D7)			< 0.05		

Comment: The rate of pediatric patients free from symptoms of reddened, swollen throat mucosa increased over the treatment period in both groups. After 7 days of treatment, the rate of pediatric patients free from symptoms in the research group (93.3%) was higher than in the control group (70%). The difference was statistically significant with $p < 0.05$.

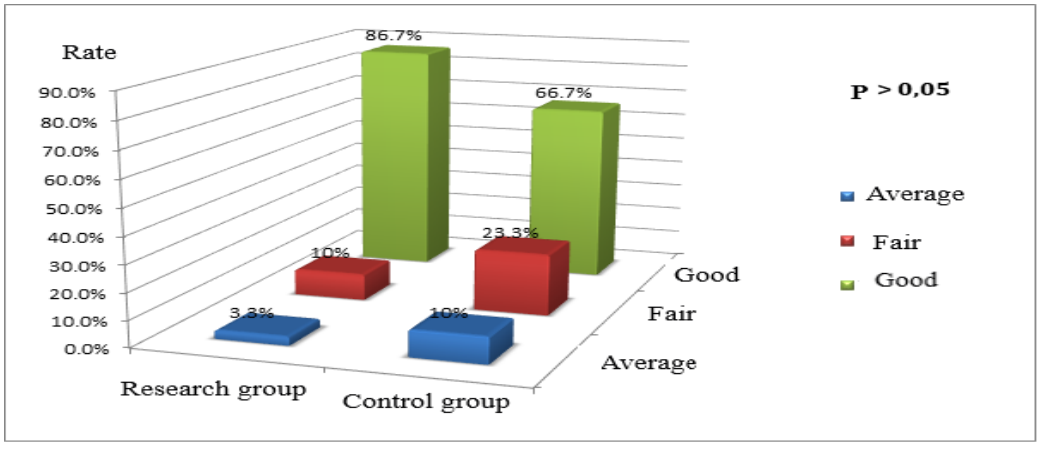

Figure 1. Overall clinical results according to modern medicine after 7 days of treatment

Comment: After 7 days of treatment, the overall treatment result was classified as good in the research group (86.7%) compared to the control group (66.7%). The average treatment result for the research group (3.33%) was lower than the control group (10%). The difference was not statistically significant with $p > 0.05$.

3.2. The side effects of "Tam ao thang" when used in children aged 2 to 5 years

Table 4. Side effects in the research group

Symptoms	Research Group (n=30)		Control Group (n=30)	
	n	Percentage (%)	n	Percentage (%)
Nausea, vomiting 30 minutes after taking medication	2	6.67	0	0
Rash, erythema, urticaria	0	0	0	0
Abdominal bloating	0	0	0	0

Comments: In the research group, 2 children (accounting for 6.67%) exhibited symptoms of nausea and vomiting 30 minutes after taking the medication.

Table 5. Some hematological indices before and after Treatment

Group / Index	Research Group (n=30)			Control Group (n=30)		
	D0	D7	p (D0-D7)	D0	D7	p (D0-D7)
Red Blood Cells (T/l)	4.46±0.29	4.53±0.29	>0.05	4.57±0.32	4.55±0.31	>0.05
White Blood Cells(G/l)	7.44±0.81	7.34±0.73	>0.05	7.23±0.69	7.22±0.71	>0.05
Neutrophils (%)	53.3±4.63	55.8±3.79	>0.05	51.2±4.95	54.02±4.7	>0.05
Lymphocytes (%)	34.6±6.03	31.5±3.6	>0.05	34.7±6.8	30.67±5	>0.05
Platelets (G/l)	216.3±36	217.2±33	>0.05	218.3±38	217.7±35	>0.05
p			> 0.05			

Comments: The results of the hematological tests (red blood cells, white blood cells, neutrophils, lymphocytes, and platelets) before and after treatment in both the research group and the control group showed changes but remained within normal limits. The differences were not statistically significant, with $p > 0.05$.

Table 6. Some biochemical indices before and after treatment

Group / Index	Research Group (n=30)			Control Group (n=30)		
	D0	D7	p (D0-D7)	D0	D7	p (D0-D7)
Ure (mmol/l)	3.58±0.33	3.6±0.29	>0.05	3.56±0.35	3.55±0.36	>0.05
Creatinin (µmol/l)	65.6±6.5	63.7±5.8	>0.05	65.8±3.58	65.1±3.93	>0.05
AST (U/L)	26.93±4.7	27.5±4.8	>0.05	27.13±3.6	26.87±3.9	>0.05
ALT (U/L)	26.8±4.7	28.4±4.6	>0.05	27.13±3.9	27.2±3.7	>0.05
p	> 0.05					

Comments: The results of the biochemical tests for liver and kidney function before and after treatment in both the research group and the control group were within normal limits for all indices. The differences were not statistically significant, with $p > 0.05$.

IV. DISCUSSION

4.1. The therapeutic effects of "Tam ao thang" in treating acute rhinopharyngitis in children aged 2 to 5 years

After 7 days of treatment, the rate of pediatric patients free from fever in the research group (96.7%) was higher than in the control group (90%), but the difference was not statistically significant with $p > 0.05$. The study used paracetamol as the base medication for fever reduction in combination with the "Tam ao thang". The remedy contains Ma hoang (Herbal Ephedra), which is pungent and warm, effective in dispersing wind-cold and inducing sweating. Ma hoang has a chemical composition rich in essential oils that increase sweating (in Traditional Medicine, this is referred to as inducing sweating). Sweating is an important thermoregulatory mechanism, as the evaporation of 1 gram of sweat from the skin's surface consumes 0.58 kilocalories of heat [9].

After 7 days of treatment, the rate of pediatric patients free from

cough in the research group was 86.7%, higher than the control group (63.3%). According to Traditional medicine, children with a deficiency of the lung are inherently vulnerable. When their protective functions are weakened or disrupted, they become susceptible to external pathogens. Wind, cold, and dryness are the primary pathogenic factors that can invade the body through the mouth, nose, or skin, causing the lung energy to lose its ability to diffuse and generate fluid, which in turn causes coughing [5]. The "Tam ao thang" has the effect of opening the lungs, stopping cough, and calming asthma. The three ingredients in the Tam ao thang help stop cough and reduce phlegm: Hanh nhan, Cam thao, and Ma hoang. Hanh nhan contains the active ingredient amygdalin, which inhibits the cough center to reduce coughing symptoms. Ma hoang mainly contains ephedrine, which relaxes smooth muscles in the respiratory tract, thus reducing coughing. Cam thao contains saponins, especially glycyrrhizin, at 10–12% in the dried herb, which has anti-inflammatory effects and helps reduce coughing symptoms.

After 7 days of treatment, the rate of pediatric patients free from phlegm in the research group was 83.3%, higher than the control group (60%), and the difference was statistically significant with $p < 0.05$. This result is higher than the study by Ta Thanh Ha, where the rate of pediatric patients free from phlegm symptoms in the research group was 77.27% after 7 days of treatment [10].

After 7 days of treatment, the rate of pediatric patients free from nasal congestion and runny nose in the research group was 90%, higher than in the control group (66.7%), and the difference was statistically significant with $p < 0.05$. According to Traditional medicine, symptoms of nasal congestion and runny nose are due to obstruction of the nasal passages. When wind-cold invades the lungs, the lung function of dispersing and descending is impaired. The combination of wind and cold causes stagnation, leading to nasal obstruction and clear runny nose. The "Tam ao thang" has the effect of dispersing wind and expelling cold, opening the lungs, stopping cough, and calming asthma [5].

The primary lesion in acute rhinopharyngitis is the acute inflammation of the nasal and pharyngeal mucosa. Clinically, endoscopic examination reveals congested and swollen nasal and pharyngeal mucosa. This is a significant symptom in diagnosis and monitoring treatment. According to Table 2, after 7 days of treatment, the rate of pediatric

patients free from symptoms of nasal mucosa congestion and nasal floor with clear mucus in the research group was 90%, higher than the control group (66.7%). This result is higher than the study by Tran Thi Yen, which reported 86.7% of cases [7]. According to Table 3, after 7 days of treatment, the rate of pediatric patients free from symptoms of reddened and swollen throat mucosa in the research group was 93.3%, higher than in the control group (70%), with a statistically significant difference of $p < 0.05$.

4.2. The side effects of "Tam ao thang" when used in children aged 2 to 5 years

The side effects observed in pediatric patients in the research group using the "Tam ao thang" were 2 out of 30 (accounting for 6.67%). The side effect such as nausea and vomiting that occurred 30 minutes after taking the medication were attributed to the pediatric patient's reluctance to take the herbal remedy, combined with throat irritation due to acute rhinopharyngitis.

The hematological indices (including white blood cells, neutrophils, lymphocytes, red blood cells, and platelets) and biochemical markers (urea, creatinine, AST, ALT) before and after treatment were all within normal limits.

V. CONCLUSION

5.1. Evaluation of the therapeutic effect of "Tam ao thang" in acute rhinopharyngitis in pediatric patients Aged 2 to 5 years

- After 7 days of treatment, the "Tam ao thang" combined with Modern medicine showed better results compared to treatment with conventional Modern medicine alone:

- The number of pediatric patients who recovered from symptoms such as cough, phlegm, sore throat, nasal congestion, runny nose, as well as fever and inflammation of the nasal mucosa in the research group was higher than in the control group receiving conventional Modern medicine treatment, with $p < 0.05$.

Classification of treatment effectiveness after 7 days in the research group: Good**:** 26/30 (86.7%); Fair**:** 3/30 (10%); Average**:** 1/30 (3.3%)

- In acute rhinopharyngitis in pediatric patients, the "Tam ao thang" is more effective in treating Cough and Phlegm syndrome associated with wind-cold type.

5.2. The side effects of "Tam ao thang" when used in children aged 2 to 5 years

- The rate of side effects such as vomiting and nausea after taking the medicine in the study group were low at 6.67% and no abnormal changes were found in

hematological and biochemical tests before and after treatment in the two groups.

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