

A Clinical Study of SJ-002

Suk-Joong Yong* and Jae-Gap Lee

Department of Internal Medicine, Yonsei University Wonju College of Medicine, Wonju, Korea

ABSTRACT

SJ-002 is a combination prescription of acetaminophen, ibuprofen, DL-methylephedrine HCl, caffeine, chlorpheniramine maleate, guaifenesin and dextromethorphan HBr.

Common cold symptoms such as headache, pharyngitis, fever, or cough were improved by oral administration of SJ-002.

This study enrolled about 30 patients, which was carried out from Jun. to Jul. 1991.

The patients were given one bottle (30 ml) of SJ-002 t.i.d by P.O for one to seven days.

1) Thirty patients(100%) had improvements with this drug.

2) There were eight patients (26.7%) with side effects. But the side effects were not serious and transient when the medication was discontinued.

Key Words: SJ-002, Clinical effect, Common cold

INTRODUCTION

The common cold means symptoms caused by "Upper Respiratory Tract Infections" Severe cold is separately treated.

The common cold is an acute respiratory disease caused by one of many viruses such as rhinovirus, coronavirus, or adenovirus.

The intensity of symptoms may vary from hour to hour. A reasonable approach is to treat the patient symptomatically, if necessary, with individual drugs. Patients suffering from common cold complain bronchitis, laryngitis, stuffy nose, runny nose, or headache etc. The common cold has been described as the most expensive single illness and the single or concomitant uses of Aspirin, ibuprofen or acetaminophen have been common.

And many studies on the synergetic effects of the concomitant administrations have been performed.

Ibuprofen, an α -methyl derivative of ibufenac as a nonsteroidal anti-inflammatory analgesic,

has still more potent action than aspirin.

Acetaminophen has been used as a popular analgesic and antipyretic. But its antiinflammatory effect isn't useful.

Antihistamines or antitussive expectorants are effective for nasal congestion, runny nose, or sneezing.

The following is our clinical results obtained from a clinical study with SJ-002 oral liquid (Table 1) provided by Samjin pharm.

MATERIALS AND METHODS

This study was performed on 30 patients with

Table 1. The composition of SJ-002

Acetaminophen	300 mg
Ibuprofen	100 mg
DL-methylephedrine HCl	12.5 mg
Caffeine anhydrous	30 mg
Chlorpheniramine maleate	2.5 mg
Guaifenesin	80 mg
Dextromethorphan HBr	15 mg

Table 2. Age and sex distribution

Age	Male	Female	Total
Under 20	—	1	1
20~30	—	2	2
31~40	4	4	8
41~50	2	6	8
51~60	3	3	6
61~70	5	—	5
Total	14	16	30

Table 3. Global improved rating

	Case(%)
1. Improved	17(56.7)
2. Moderately improved	10(33.3)
3. Slightly improved	3(10.0)
4. Unchanged	—
5. Aggravated	—

URI symptoms at the Wouju Christian Hospital, Wonju College of Medicine, Yonsei University.

The ratio of male to female was about 14 to 16 (Table 2).

Clinical results were determined in 5 classifications according to the extent of the improvements.

Blood tests and urine tests on erythrocyte, leucocyte, S-GOT, S-GPT, ALP and creatinine were performed to see whether any side effects occurred.

RESULTS

All thirty patients (100%) had improvements with SJ-002 (Table 3).

Almost cold symptoms were relieved 3 days after administration 8 patients complained side effects with this preparation. 7 patients of them (23.3%) had dizziness, nausea, or vomiting as side effects.

But they were not serious. The other one patient complained nausea and dyspepsia, so discontinued the medication. The side effect was

Table 4. Overall safety rating

	Case(%)
1. No side effect	22(73.4)
2. Slight side effect dose unchanged	7(23.3)
3. Dose reduced	—
4. Administration stopped (side effect disappeared)	1(3.3)
5. Administration stopped (side effect persisted)	—

Table 5. Global utility rating

	Case(%)
1. Excellent useful	11(36.7)
2. useful	16(53.3)
3. Slightly useful	3(10.0)
4. Seems not to be useful	—
5. Underirable	—

transient (Table 4).

There was no significant changes or abnormality on routine hematology, urinalysis and blood chemistry.

In a conclusion, all 30 patients were relieved from common cold symptoms due to URI and 11 patients, especially, had significant improvements with SJ-002 (Table 5).

DISCUSSION

Nicholson and his colleagues synthesized Ibuprofen, an α -methyl derivative of ibufenac as a nonsteroidal anti-inflammatory analgesic by reducing toxicity of ibufenac, one of arylalkanoic acid compounds (Adams *et al.*, 1963).

The racemic compound of ibuprofen has still stronger anti-inflammatory, analgesic and antipyretic effects than aspirin. Much more effective actions of ibuprofen have been reported comparing with Phenylbutazon (Inem, 1967; Adams, 1969; Masumote, *et al.*, 1970). It exerts analgesic, anti-inflammatory and antipyretic effects by inhibiting prostaglandin synthetase (Busson, 1986).

Acetaminophen was first used in medical therapy by von Mering in 1883 and has been used as a popular analgesic and antipyretic drug (ameer & Greemblatt, 1977)

Acetaminophen is a weak inhibitor of prostaglandin biosynthesis, although there is some evidence to suggest that it may be more effective against enzymes in the CNS than those in the periphery.

Methylephedrine is a sympathomimetic bronchodilator (chen & Schmidt, 1930).

It has similar bronchodilating effect to ephedrine and still weaker raising of blood pressure and stimulating effects on CNS system than ephedrine.

Methylephedrine has been used, either alone or in conjunction with other agents, in the symptomatic relief of nasal congestion associated with the common cold, Hay-fever, rhinitis, or sinusitis.

Caffeine stimulates the central nervous system (CNS), act on the kidney to produce diuresis, stimulate cardiac muscle, and relax smooth muscle. Caffeine produces an increased capacity for sustained intellectual effort and decreases reaction time.

Caffeine stimulates less drowsiness, less drowsiness, less fatigue, and more rapid and clearer flow of thought.

Chlorpheniramine Maleate is one of widely used potent antihistamines and causes a moderate degree of sedation (Centekin, 1983).

Guaifenesin is reported to reduce the viscosity of tenacious sputum and is used as an expectorant (While, 1977; Kuhn, 1982)

Guaifenesin is effective in productive as well as nonproductive cough, but is of particular value in dry, nonproductive cough which tends to injure the mucous membranes of the air passages.

Dextromethorphan HBr is a methylated dextro-isomer of levopropyl, unlike its analgesic counterpart, it has no significant analgesic properties and does not depress respiration or predispose to addiction (Matthys, 1983)

Its effectiveness in patients with pathological cough has been demonstrated in controlled studies and its potency is similar to codeine.

This drug had been widely used as an antitussive.

Compared to codeine, dextromethorphan HBr, produces fewer subjective and gastrointestinal side effects.

As a result of this clinical study, this treatment (SJ-002) was effective against all the symptoms of coryza without severe side effects.

CONCLUSIONS

The activity and acceptability of SJ-002 in the treatment of common cold was investigated through the patients with URI symptoms at Wonju hospital, Yonsei Univ. Wonju College of Medicine.

Statistical analysis of the results showed:

1) All patients enrolled had improvement with oral administration of SJ-002. SJ-002 was considered to be an effective treatment for the common cold.

2) Side effects like urticaria or constipation occurred in 8 patients which was transient because such side effects was immediately reverted to normal with the discontinuation of the medication.

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= 국문초록 =

SJ-002의 임상적 효과

연세대학교 원주의과대학 내과학교실

용 석 중* · 이 재 갑

급격한 기온의 변화가 심한 환절기에 우리는 감기라는 상기도 감염에 잘 걸리게 된다. 비록 그 증상이 중하지 않고 또 안정을 하면서 10일정도가 되면 자연히 치유된다 할지라도 때로는 중한 합병증으로 고생하는 수가 있으며 또 두통, 발열, 기관지염, 인후통등으로 인하여 활동이 제한되며 활동능력이 저하되기도 한다.

1991년 6월 20일부터 7월 29일까지 원주 기독병원 내과에서 치료를 받은 30명의 환자에게 1~7일간 SJ-002를 30 ml×3/day를 투여하여 치료한 결과 다음과 같은 유의성 있는 결론을 얻었다.

상기도 감염증 환자 30명 (100.0%)모두에게서 증상의 호전을 보였다.

부작용은 8명 (26.7%)에서 나타났으며 투약을 중지함으로써 모두 소실되었다.

1. 본 연구에서는 상기도 감염증 환자 30명 (100.0%) 모두에게서 임상증상의 전반적 개선이 관찰되었으며 특히 감기의 재증상에서 나타날 수 있는 증상등의 치료에 유효성이 있는 복합액제라고 생각된다.

2. 복용하는 동안 발진, 변비등의 경미한 부작용 환자 8명이 나타났지만 투약을 중지함으로써 모든 부작용들이 소실되었다.

SJ-002 (1병 30 ml)의 조성은 다음과 같다.

Acetaminophen	300 mg
Ibuprofen	100 mg 12.5 mg
DL-methylephedrine HCl	30 mg
Caffeine anhydrous	2.5 mg
Chlorpheniramine maleate	80 mg
Guaifenesin	15 mg
Dextromethorphan HBr	