

Clinical Effects of SJ-002 on URI

—Upper Respiratory Tract Infection—

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ABSTRACT

SJ-200 is an oral liquid preparation of acetaminophen, ibuprofen, D1-methyleph edrine HCl, caffeine, chlorpheniramine maleate, guaifenesin and dextromethorphan HBr, which is indicated when there is a need to improve various cold symptoms such as headache, sore throat, fever, or cough etc.

Thirty patients was enrolled for this study fro June to July, 1991. They were given one bottle (30 ml) of SJ-200 t.i.d dy P.O for an average of one to seven days.

1) Twenty-eight patients (84.8%) were relieved from the symptoms of upper respiratory tract infection.

2) Side effects with this preparation occured in 8 patients(924.2%) but in four patients, they were mild, which wee transiently by the discontinuation f the medication.

Key Words: SJ-002, Upper respiratong infection

INTRODUCTION

The common cold is a mixture of symptoms affecting the upper respiratory tract.

It is also called a "cold", acute rhinitis, infectious rhinitis, coryza, or catarrh.

The symptoms, which are usually acute and self limiting, may be caused by one of many viruses such as rhinovirus, coronavirus, or adenovirus.

A cold may present symptoms, individually or in combination of, the nose (rhinitis), throat (pharyngitis), larynx (laryngitis) or bronchi (bronchitis).

Aspirin has been widely used to treat cold symptoms such as headache, pharyngitis, or myalgia etc.

The single uses of ibuprofen or acetaminophen or their concomitant administration has been common, too.

Many studies regarding their synergetic effects in combination products have been actively carried out.

Ibuprofen <2-(4-isobutylphenyl) acetic acid>, a nonsteroidal anti-inflammatory drug is one of phenylalkanoic acid derivatives and used for rheumatoid arthrosis or osteoarthritis as an excellent substitute for Aspirin. Its toxicity to stomach is much weaker than that of Aspirin.

Acetaminophen, a derivative of p-aminophenol, has potent analgesic and antipyretic effects, and weak antiinflammatory action. Infrequent gastric

Table 1. The composition of SJ-002 (30 ml)

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	3	—	3
20~30	4	2	6
31~40	1	1	2
41~50	7	1	8
51~60	4	1	5
60~70	6	3	9
Total	25	8	33

hemorrhage or uric acid secretion with this drug has been reported.

Antihistamines or antitussive expectorants are effective for relieving cold symptoms such as stuffy nose, runny nose, or sneezing.

Here is a report regarding the effectiveness of SJ-002 on upper respiratory tract infections.

MATERIALS AND METHODS

33 patients at Kyungpook Nat'l hospital suffering from the various symptoms of cold such as pharyngitis, bronchitis, or fever etc were given SJ-002 oral liquids three times (30 ml per time) a day for one to seven days from Jun. 20, 1991 to Jul. 30, 1991.

The therapeutic effects with this preparation were evaluated in 5 classes according to their improvements of symptoms.

Blood tests and urine tests on erythrocyte, leucocyte, S-GOT, S-GPT, ALP and creatinine should be taken to see whether side effects with this preparation occur or not.

RESULTS

Out of 33 patients enrolled, 28 (84.8%) showed improvements of cold symptoms with SJ-002, 5 (15.2%) didn't have improvement by oral administration of this drug.

Side effects with SJ-002 occurred in 8 patients.

2 patients among them had nausea or vomiting but they were not serious. Other 2 patients showed slight side effects but they were transient with the discontinuation of medication.

Table 3. Global improved rating

	Case(%)
1. Improved	11(33.3)
2. Moderately improved	10(30.3)
3. Slightly improved	7(21.2)
4. Unchanged	5(15.2)
5. Aggravated	

Table 4. Overall safety rating

	Case(%)
1. No side effect	25(75.8)
2. Slight side effects dose unchanged	29 6.0)
3. Dose reduced	2(6.0)
4. Administration stopped (side effect disappeared)	4(15.2)
5. Administration stopped (side effect persisted)	

Table 5. Global utility rating

	Case(%)
1. Excellent useful	10(30.3)
2. Useful	12(36.4)
3. Slight useful	6(18.15)
4. Seems not be useful	5(15.15)
5. Undesirable	

And the other A patients discontinued medication because of convulsion or diarrhea.

When blood test or urine test after oral administration are performed, and serious changes in the counts of erythrocytes, leucocytes, S-GOT, S-GPT, ALP, or Creatinine weren't observed.

Examining whole improvements each patient had, SJ-002 was effective in 28 patients out of 33 patients (84.8%) with URI and 10 patients among them had significant improvements (Table 5).

DISCUSSION

A nonsteroidal anti-inflammatory drug, Ibuprofen, has been in use for the treatment of rheumatic diseases Busson, 1986. Ibuprofen was

synthesized in 1963 and is well absorbed by oral administration. And over 50% is excreted in the urine as oxidized metabolites Adams *et al.*, 1963; Adams, 1969; Masumoto *et al.*, 1970.

Its racemie has much stronger effects, compared with Aspirin. Ibuprofen exerts analgesic, anti-inflammatory, and antipyretic properties by inhibiting prostaglandin synthetase Idem, 1967. The animal tests with Inuprofen proved its more potent action over phenylbutazon.

Acetaminophen is a main metabolite of acetanilide or phenacetin and effective as antipyretic analgesic drug. Acetaminophen produces analgesia by elevation of the pain threshold and antipyresis by vasodilation peripheral vessels through action on the hypothalamic heat regulating center.

Its toxicity is weaker than acetanilide.

Methylephrine has similar pharmacological effect to ephedrine Chen & Schmidt, 1930. It's used for hypotension or bronchial asthma by oral administration as a sympathetic bronchodilator.

Caffeine is xanthine derivative, stimulates the central nervous system (CNS), act on the kidney to produce diuresis, stimulate cardiac muscle and relax smooth muscle. Traditionally, caffeine has been considered the most potent of the methylxanthines. Small dose of caffeine causes less drowsiness, less fatigue, and a more rapid and clearer flow of thought, Caffeine produces an increased capacity for sustained intellectual effort.

Chlorpheniramine maleate is a H receptor antagonist and an alkylamine derivative with the actions and uses of the antihistamines.

Chlorpheniramine is generally used for hay-fever, rhinitis, otitis media etc Kuhn, 1982.

By increasing respiratory tract fluid, guaifenesin reduces the viscosity of tenacious secretions and acts as an expectorant. The drug 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 Mattys, 1983; Centekin, 1983

Dextromethorphan HBr is the d-isomer of the codeine analog of levorphanol, however, unlike the l-isomer, it has no analgesic or addictive properties While Yeates, 1977.

The drug acts on medulla oblongata to elevate the threshold for coughing.

Its structure is very similar to Morphine and its potency as antitussive is nearly equal to that of codeine While Yeates, 1977.

The concomitant uses of antipyretic analgesic drug, antihistamine and antitussive expectorant are continued to be studied.

As a conclusion of this study regarding SJ-002 clinical effects on URI, SJ-002 proved improvements of cold symptoms and no serious effects, so SJ-002 is a suitable preparation for common cold due to upper respiratory tract infection.

CONCLUSION

The results of the study carried out from Jun. 20 to Jul. 30, 1991 in Kyungpook Nat'l Hospital are shown as follows.

1) 28 patients with URI were relieved from the common cold symptoms.

2) Side effects with this preparation occurred in 8 patients. 4 patients of them discontinued the medication and the other patients had mild side effects which didn't give significant effects on the medication. SJ-002 composed of several effective ingredients is expected to be very useful for patients.

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=국문초록=

상기도감염증에 대한 SJ-002액의 임상적 고찰

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1991년 6월 20일부터 7월 30일 까지 경북대학병원 내과에 내원한 33명의 환자를 대상으로 상기도 감염증에 의한 인후통, 기관지염 및 발열이 있는 환자에게 1~7일간 SJ-002액을 1회 30 ml 1병씩 1일 3회 투여하는 방식에서 임상실험을 실시하였다.

치료효과의 판단은 증세의 호전동도를 5단계로 구분하여 평가하였다.

부작용 여부를 알아보기 위하여 약물투여후 백혈구수, 적혈구수, 헤모글로빈수 및 혈관관수등의 혈액검사와 S-GOT, S-GPT, ALP 및 Creatinine등의 형청생화학 검사 및 뇨검사도 시행하였다.

전체 33명의 상기도 감염증 환자에게 SJ-002를 투여한 결과 28명 (84.8%)에게서 증상의 호전을 보였으며 5명 (15.2%)은 치료전과 동일하였다.

환자 각각의 임상적 증상 개선은 SJ-002투여 3일째에 거의 개선되었다.

치료도중 부작용은 모두 8명 (24.2%)에서 발생하였다. 이중 2명 (6.0%)은 오심 및 구토등의 부작용이 발생하였으나 투약에 영향을 미치는 정도가 아니었다. 2명 (6.0%)은 경미한 부작용이 발행하였으나 이는 투약을 중지하면 곧 소실되었고, 4명은 경련 및 설사등의 부작용이 발생하여 투약을 중지 하였다.

또 투약후 실시한 혈액검사 및 소변 검사상 적혈구수, 백혈구수, S-GOT, S-GPT, ALP, Creatinine의 증가나 단백뇨 및 당뇨등의 소견을 볼 수 없었다. 전체적인 개선도와 전반적인 안정도를 종합적으로 판단하여 볼 때 SJ-002를 상기도 감염증 환자에게 투여시 28명중 84.8%에게 유용했으며 특히 10명 (30.0%)은 임상증상이 현저히 호전되었다.

감기에 의한 인후통, 기관지염, 발열 및 기침등의 증상을 개선시키기 위해 투여한 SJ-002의 임상 실험결과 상기도 감염을 포함한 감기의 제증상을 호전시킴을 알 수 있었고, 여러가지 유의성 있는 복합성분으로 처방된 이액제의 유용성이 한층 커질 것으로 기대되어진다.

(성분 및 함량)

1병(30 ml)중

Acetaminophen	300 mg
Ibuprofen	100 mg
DL-methylephedrine HCl	12.5 mg
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