

Treatment of the Common Cold

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Abstract

Background : Common colds are usually treated by the patients themselves with over-the-counter (OTC) cold medications. Many cough and cold remedies are available and sold freely without prescription. The authors conducted a study to compare the efficacy, adverse effects, the quality of life (QOL) and the patient's opinion and appreciation on the drugs (POD) between Dayquil®/Nyquil® and Actifed DM® plus paracetamol syrup.

Method : In this prospective, investigator-blinded clinical trial, 120 patients, aged between 15 and 60 years old, with common colds within 72 hours, who accepted the trial and gave informed written consent, were randomized into two treatment groups. One patient was excluded due to evidence of bacterial infection. Fifty-nine patients were treated with Dayquil®/Nyquil® (D/N group), while the other 60 patients had Actifed DM® plus paracetamol (ADM/P group) for three days. On day 1 the patient's demographic data (sex, age, body weight, blood pressure, co-existing diseases/conditions, drug use, and allergy to any drugs), the most prominent symptoms and its duration were recorded. All patients were screened for bacterial infection by physical examination, complete blood count and sinus radiographs. The symptoms (nasal obstruction, rhinorrhea, sneezing, cough, sore throat, fever and headache) and signs (injected nasal mucosa, nasal discharge and pharyngeal discharge) were scored, based on 4-point scale (0 to 3), on days 1 and 4. Changing of the symptoms and QOL were recorded on the diary card. The patient's opinion and appreciation on the drugs (POD) was assessed on day 4. The effectiveness (the ability to lessen the symptoms and signs), QOL and POD between two treatments were compared.

Results : The demographic data between the two groups were similar. The four most common prominent symptoms of common colds in our series were cough (47.9%), sore throat (26.17%), rhinorrhea (8.4%) and headache (8.4%). However, both treatments were equally effective in lessening the symptoms ($P = 0.426$) and signs ($P = 0.716$) of common cold from days 1 to 4. The adverse effects were significantly higher in ADM/P group than in D/N group ($p = 0.006$). In contrast, QOL in terms of alertness, freshness and sound sleep improved from day 1 to day 3 in both treatments, but the overall day-3 score was significantly higher in the D/N group than the ADM/P group (1.85 ± 1.83 ; 1.25 ± 1.94 ; $p = 0.024$). POD in terms of convenience, flavour of drug, effectiveness of the drug and a need to repeat the drug assessed on day 4, was also significantly higher in the D/N group than the ADM/P group (10.68 ± 2.56 ; 8.92 ± 2.27 ; $p < 0.001$)

Conclusion : Dayquil®/Nyquil® are as effective as Actifed DM® plus paracetamol in controlling the symptoms and signs of the common cold, but have fewer adverse effects. The quality of life assessed during the use of the drugs was significantly higher in the Dayquil/Nyquil group, and according to the patients, they preferred Dayquil/Nyquil more than Actifed DM plus paracetamol.

Key word : Common Cold, Rhinitis, Medical Treatment, Viral Infection

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The common cold is the most common cause of acute rhinitis. It is probably the most common infectious disease in humans. Children under the age of 5 years are the most susceptible. On average, a child or an adolescent may have 3 to 5 colds a year, depending on contact with certain environmental changes⁽¹⁾.

The disease is caused by various viruses. Rhinovirus is the most common infectious agent found in patients with common colds. Other viruses include coronavirus, para-influenza virus, respiratory syncytial virus, adenovirus and more⁽²⁾. Minor epidemics occur during the winter and rainy months and spread rapidly among susceptible persons by droplet contact from sneezing. Chilling of the body and fatigue as well as crowded living quarters are predisposing factors⁽³⁾. In a recent cohort study, Takkouche et al (2001) suggested that psychological stress is also a risk factor of the common cold⁽⁴⁾.

The pathogenesis of the common cold is associated with inflammation of the nasal mucous membrane with polymorphonuclear cells and increased levels of inflammatory cytokines and mediators in nasal mucosa^(5,6). The typical symptoms of the common cold are well known to ordinary people. It begins with a feeling of irritation and a burning sensation in the nasopharynx, sneezing and copious nasal discharge then follow. Mild fever with malaise and myalgia are usually present. As the disease progresses, the nose becomes more obstructed and the discharge becomes mucopurulent. Headache is a common symp-

tom during the first two days. A sore throat is not a characteristic complaint but a cough is more commonly found. It ranges from 83 per cent within the first 48 hours of the cold to 26 per cent on day 14⁽⁷⁾. The cough appears to arise from the stimulation of the cough reflex in the upper respiratory tract by postnasal drip, clearing the throat or both⁽⁷⁾. When uncomplicated, the common cold is self limited. Most symptoms subside in 4-5 days and the nose returns to normal in 6-7 days. However, when the condition is complicated by secondary invasion of virulent bacteria, the symptoms persist and becomes worse. Then, there may be symptoms and signs of sinusitis, bronchitis or pneumonia^(8,9).

Diagnosis of the common cold is made upon the characteristic symptoms and signs as described above. In such cases, diagnostic testing is not indicated, because it has a low yield. For instance, in immunocompetent patients with those symptoms and signs, more than 97 per cent of chest radiographs will be normal⁽¹⁰⁾. Moreover, in recent investigations, the common cold was considered as a viral rhinosinusitis form which often cannot be distinguished clinically and radiographically from bacterial rhinosinusitis at the beginning^(11,12).

There is no known specific treatment for the common cold and no hard and fast therapeutic rule can be laid down for all individuals. Therapy varies from one patient to another. However, general and local support and palliative treatment can mitigate the

severity and complication⁽¹³⁾. Bed rest in an even temperature of 18-20°C with 45 per cent humidity, adequate fluid intake and regular diet are effective measurements. Moreover, heat provided to the patient, generally by a hot bath and locally directly to the nasal mucosa by steaming water inhalation (with or without tincture benzoin) can reduce the nasal symptoms⁽¹³⁾. The combination of an analgesic, antihistamine, decongestant and antitussive in the form of over-the-counter (OTC) tablets or syrups is often used to lessen the severity of symptoms and improve the quality of life (QOL). However, these OTCs contain different ingredients and have different formulation.

In Thailand, Actifed DM® (Wellcome) containing tripolidine 1.25 mg, pseudo-ephedrine HCl (PSE) 30 mg and dextromethorphan HBr (DMP) 10 mg in 5 ml, is widely used as a well-known OTC cough syrup for the common cold. However, Vicks Dayquil® (paracetamol 650 mg, PSE 60 mg and DMP 20 mg in 30 ml) and Vicks Nyquil® (paracetamol 1000 mg, PSE 60 mg, DMP 30 mg and doxylamine succinate 1.25 mg in 30 ml), the products of Procter & Gamble Co, North Carolina, USA have been approved and were registered in the USA in 1976 and are known as the OTC syrup for relieving cold symptoms.

The purpose of this study was to compare the efficacy and safety of Vicks Dayquil/Nyquil® (D/N) with Actifed DM® plus paracetamol syrup (ADM/P) in patients with common colds. The other objectives included the comparison of QOL and POD in patients using D/N and those with ADM/P.

PATIENTS AND METHOD

This study was designed as an investigator-blinded, prospective randomized clinical trial conducted in the ENT outpatient department of King Chulalongkorn Memorial Hospital, Thai Red Cross Society, between February 1, 2001 and January 31, 2002. This study was reviewed and approved by the ethics committee of the Faculty of Medicine, Chulalongkorn University.

Population

Any patients aged between 15 and 60 years old, who were diagnosed with common colds within 72 hours and with at least four symptoms (nasal obstruction, rhinorrhea, cough and fever with or without headache) were recruited into the study. However, patients with a) evidence of bacterial infection b) severe systemic disease c) allergy to the study drugs

and their ingredients and d) pregnancy or nursing baby, were excluded from the study.

One hundred and twenty eligible patients with signed consent, entering in the study were randomly assigned to receive either Vicks Dayquil 30 ml three times a day plus Vicks Nyquil 30 ml before bed time for 3 days (D/N group) or Actifed DM 10 ml plus 30 ml. paracetamol syrup four times a day for 3 days (ADM/P group)

One patient in the D/N group who had symptoms and signs of bacterial rhinosinusitis with elevated white blood cell count (15,000 cell/dl) was excluded from the study leaving 59 patients in the D/N group (men 13, women 46, mean age of 37.2 ± 11.66 years, range 16-59 years). In the ADM/P group all 60 patients (men 19, women 41; mean age of 35.4 ± 12.01 years; range 15-60 years) were evaluable.

The demographic data, most prominent symptoms, duration of symptoms, associated diseases, drug uses and laboratory findings (the complete blood count and paranasal sinus radiographs) were recorded on day 1. The data of both treatment groups were comparable (Table 1, 2)

Clinical evaluation

The symptoms of nasal obstruction, rhinorrhea, sneezing, cough, sore throat, fever and headache were evaluated and the severity was graded based on a 4-point scale: 0 (no symptoms) 1 (mild symptoms), 2 (moderate symptoms) and 3 (severe symptoms). The symptoms were recorded twice daily in the morning (07.00 am) and in the evening (08.00 pm) by the patients themselves on the diary card on day 1, 2 and 3 and in the morning of day 4. The cards were returned to the investigator at the second visit (Table 3).

The signs of nasal discharge, injected nasal mucosa and pharyngeal discharge were also evaluated and were graded based on a 4-point scale by the investigator on day 1 and 4 (Table 4).

The QOL was evaluated in three aspects: alertness, freshness, and a good sleep. Each item was graded as worse (-1), same (0), better (+1) and much better (+2) compared to the conditions on the day before treatment. It was recorded by the patients in their diary cards on days 1, 2 and 3 (Table 5).

The adverse effects of the drugs in the D/N and ADM/P group were assessed by the investigators from the patient's reports on day 4 (Table 6).

Finally, the last goal was to evaluate the patient's opinion and appreciation of the study drugs

Table 1. Demographic data of patients in frequency and percentage.

| Variable | D/N (59) | | ADM/P (60) | | Overall (119) | |
|----------------------|---------------|------|---------------|------|---------------|------|
| | N | % | N | % | N | % |
| Sex | | | | | | |
| Male | 13 | 22.0 | 19 | 31.7 | 32 | 26.8 |
| Female | 46 | 78.0 | 41 | 68.3 | 87 | 73.2 |
| Age (years) | | | | | | |
| 1-15 | - | - | 1 | 1.7 | 1 | 0.9 |
| 16-30 | 21 | 35.6 | 23 | 38.3 | 44 | 36.9 |
| 31-45 | 20 | 33.9 | 21 | 35 | 41 | 34.5 |
| 46-60 | 18 | 30.0 | 15 | 25 | 33 | 27.7 |
| Mean (SD) | 37.2 (11.66) | | 35.5 (12.31) | | 36.4 (12.2) | |
| Physical examination | | | | | | |
| Mean (SD) | | | | | | |
| Systolic BP | 116.8 (11.81) | | 116.3 (13.65) | | 116.5 (13.2) | |
| Diastolic BP | 74.8 (10.56) | | 74.2 (8.49) | | 74.5 (9.56) | |
| Pulse rate | 79.9 (9.94) | | 81.5 (11.05) | | 80.7 (10.36) | |
| Body weight | 58.1 (10.06) | | 54.3 (8.93) | | 56.2 (9.68) | |

Table 2. Medical history and diagnosis in frequency and percentage.

| History of diagnosis | D/N (59) | | ADM/P (60) | | Overall (119) | |
|--------------------------------|----------|------|------------|------|---------------|------|
| | N | % | N | % | N | % |
| Most prominent symptom | | | | | | |
| Rhinorrhea | 3 | 5.1 | 7 | 11.7 | 10 | 8.4 |
| Nasal obstruction | 7 | 11.9 | 2 | 3.3 | 9 | 7.6 |
| Cough | 30 | 50.8 | 27 | 45.0 | 57 | 47.9 |
| Sore throat | 13 | 22.0 | 18 | 30.0 | 31 | 26.1 |
| Fever | 0 | 0.0 | 2 | 3.3 | 2 | 1.7 |
| Headache | 6 | 10.2 | 4 | 6.7 | 10 | 8.4 |
| Duration of having symptoms | | | | | | |
| 1 day | 15 | 25.4 | 21 | 35.0 | 36 | 29.2 |
| 2 days | 44 | 74.6 | 39 | 65.0 | 83 | 69.8 |
| Associated diseases/conditions | | | | | | |
| Smoking | 1 | 1.7 | 0 | 0 | 1 | 0.8 |
| Drug allergy | 1 | 1.7 | 6 | 0 | 1 | 0.8 |
| Other diseases | 6 | 10.2 | 5 | 8.3 | 11 | 9.1 |
| Drug use | 3 | 5.1 | 4 | 6.7 | 7 | 5.9 |
| Paranasal sinus radiographs | | | | | | |
| Abnormal | 20 | 33.9 | 12 | 20.0 | 32 | 26.9 |

(POD) in four aspects: 1) convenience of drug use, 2) flavour of drug, 3) effectiveness of drug and 4) would repeat use of the drug whenever they catch a cold. Each aspect was also graded based on a 4-point scale: 1 (not convenient, not satisfied with the flavour, not effective and would not repeat use of the drug), 2 (slight), 3 (much) and 4 (very much). These were assessed by the patients on day 4 (Table 7).

Statistical methods

The data were entered by Excel and transformed to SPSS format. They were edited and cleaned before analysis. SPSS 9.01 was used to analyze the data. Descriptive statistics was used to describe percentage, mean and SD. Mann-Whitney U test and Wilcoxon signed rank test were used to compare the scores for two independent and two dependent groups

Table 3. Mean score of symptoms by patients on day 1 and day 4.

| | D/N (59) | | | ADM/P (60) | | |
|------------------------|-------------|-------|---------|-------------|-------|---------|
| | Day 1 | Day 4 | P | Day 1 | Day 4 | P |
| Obstruction | 1.90 | 0.59 | < 0.001 | 1.80 | 0.78 | < 0.001 |
| Rhinorrhea | 1.81 | 0.54 | < 0.001 | 1.62 | 0.60 | < 0.001 |
| Sneezing | 1.36 | 0.37 | < 0.001 | 1.38 | 0.33 | < 0.001 |
| Cough | 2.31 | 1.08 | < 0.001 | 2.32 | 1.1 | < 0.001 |
| Sore throat | 2.05 | 0.85 | < 0.001 | 2.12 | 1.02 | < 0.001 |
| Fever | 1.44 | 0.24 | < 0.001 | 1.43 | 0.15 | < 0.001 |
| Headache | 1.58 | 0.61 | < 0.001 | 1.68 | 0.53 | < 0.001 |
| Overall | 1.78 | 0.61 | < 0.001 | 1.76 | 0.65 | < 0.001 |
| Difference Day 1-Day 4 | 1.17 (0.49) | | | 1.11 (0.56) | | 0.426 |

Table 4. Signs at first visit (Day 1) and last visit (Day 4) in percentage.

| Sign score | D/N (59) | | ADM/P (60) | | P-value |
|---|-----------------|-------------|-----------------|-------------|---------|
| | Day 1 | Day 4 | Day 1 | Day 4 | |
| Nasal discharge | | | | | |
| 0 | 0 | 40.7 | 0 | 31.7 | |
| 1 | 27.1 | 44.1 | 31.7 | 51.7 | |
| 2 | 64.4 | 11.9 | 61.7 | 15.0 | |
| 3 | 8.5 | 3.4 | 6.7 | 1.7 | |
| Mean (SD) | 1.81(0.57) | 0.78 (0.79) | 1.75 (0.57) | 0.87 (0.72) | 0.252 |
| Injected mucosa | | | | | |
| 0 | 0 | 11.9 | 0 | 5 | |
| 1 | 8.5 | 71.2 | 6.7 | 71.7 | |
| 2 | 83.1 | 16.9 | 78.3 | 21.7 | |
| 3 | 8.5 | 0 | 15.0 | 1.7 | |
| Mean (SD) | 2.0 (0.42) | 1.05 (0.54) | 2.08 (0.46) | 1.2 (0.55) | 0.629 |
| Pharyngeal discharge | | | | | |
| 0 | 0 | 30.5 | 0 | 31.7 | |
| 1 | 28.8 | 39.0 | 16.7 | 35.0 | |
| 2 | 55.9 | 25.4 | 61.7 | 23.3 | |
| 3 | 15.3 | 5.1 | 21.7 | 10.0 | |
| Mean (SD) | 1.86 (0.66) | 1.05 (0.88) | 2.05 (0.62) | 1.12 (0.98) | 0.521 |
| Total score | | | | | |
| Mean (SD) | 1.89 (0.39) | 0.96 (0.62) | 1.96 (0.40) | 1.04 (0.65) | |
| Day 1 vs Day 4 | P-value < 0.001 | | P-value < 0.001 | | |
| Difference between Day 1- Day 4: Mean (SD) | 0.93(0.57) | | 0.90 (0.60) | | 0.716 |

respectively. The analysis of variance (ANOVA) with repeated measure was used to compare the score change over time.

RESULTS

The demographic data in D/N and ADM/P group were comparable. Blood pressure, pulse rate and body weight are shown in Table 1. For all 119 patients, the five most prominent symptoms were

cough 57 (47.9%), sore throat 31 (26.1%), rhinorrhea 10 (8.4%), headache 10 (8.4%) and blocked nose 9 (7.6%). The duration of symptoms before entering the study was one day (30.2%) or two days (69.8%). The prominent symptoms and duration of symptoms in each treatment group are displayed in Table 2.

Concurring on associated diseases, only one patient in the D/N group and in the total series smoked cigarettes (3 cigarettes/day). Six patients from the D/N

Table 5. Percentage of the level of quality of life (QOL) in Day 1, Day 2 and Day 3.

| QOL | D/N (59) | | | ADM/P (60) | | |
|-------------------|------------|-------------|-------------|------------|-------------|-------------|
| | Day 1 | Day 2 | Day 3 | Day 1 | Day 2 | Day 3 |
| Alertness | | | | | | |
| Worse | 6.8 | 11.9 | 6.8 | 15 | 18.3 | 15 |
| The same | 79.7 | 55.9 | 47.5 | 80 | 63.3 | 53.3 |
| Better | 13.6 | 28.8 | 39 | 5 | 18.3 | 28.3 |
| Much better | 0 | 3.4 | 6.8 | 0 | 0 | 3.3 |
| Freshness | | | | | | |
| Worse | 6.8 | 8.5 | 8.5 | 20 | 23.3 | 11.7 |
| The same | 72.9 | 42.4 | 35.6 | 68.3 | 41.7 | 35 |
| Better | 20.3 | 45.8 | 47.5 | 11.7 | 35 | 51.7 |
| Much better | 0 | 3.4 | 8.5 | 0 | 0 | 1.7 |
| Good sleeping | | | | | | |
| Worse | 1.7 | 11.9 | 1.7 | 11.7 | 5 | 5 |
| The same | 49.2 | 30.5 | 25.4 | 53.3 | 41.7 | 40 |
| Better | 47.5 | 49.2 | 61 | 33.3 | 48.3 | 43.3 |
| Much better | 1.7 | 8.5 | 11.9 | 1.7 | 3 | 11.7 |
| Overall Mean (SD) | 0.7 (1.21) | 1.22 (1.97) | 1.85 (1.83) | 0.7 (1.36) | 0.65 (1.72) | 1.25 (1.94) |

Using one-way ANOVA with repeated measure (p-value = 0.024)

Table 6. Adverse effects.

| Adverse effect | D/N (59) | | ADM/P (60) | | Overall (119) | |
|----------------|----------|------|------------|------|---------------|------|
| | N | % | N | % | N | % |
| No | 54 | 91.5 | 42 | 70.0 | 96 | 80.7 |
| Yes | | | | | | |
| Insomnia | 3 | 5.1 | 4 | 6.7 | 7 | 5.9 |
| Drowsiness | 2 | 3.4 | 14 | 23.3 | 16 | 13.4 |

Using Chi-square test $\chi^2 = 7.51$; p-value = 0.006

group and five from the ADM/P group had diseases other than the common cold. Four from each treatment group suffered from mild to moderate hypertension in which six required antihypertensive drugs, one patient from the D/N group had hyperlipidemia requiring antilipid medication and one patient from each group had mild to moderate non-progressive sensorineural hearing loss requiring no treatment.

Complete blood count (CBC) was performed to screen for bacterial infection. Patients with a white blood count (WBC) above 10,000 cell/dl together with symptoms and signs of bacterial infection were excluded from the study. Only one patient from the D/N group was excluded by these criteria.

Paranasal sinus radiographs showed abnormality in 32 out of 119 cases (26.9%) or 33.9 per cent and 20 per cent in the D/N and ADM/P group respec-

tively. The abnormal radiographs including thickening of the maxillary mucoperiosteum in 16 cases (27.1%) and 10 (16.7%) cloudy ethmoid sinuses in 2 cases (3.4%) and 2 (3.3%) and air-fluid level in 2 cases (3.4%), and 0 case (0%) were observed in the D/N and ADM/P group respectively (Table 2).

The symptoms recorded by the patients themselves were evaluated. The scores of each symptom and the overall on day 4 were significantly decreased (compared to day-1 scores) in both treatment groups. (Wilcoxon-Signed-Rank Test) However, with the Mann-Whitney U test there was no difference between the D/N group and ADM/P group (p = 0.426) (Table 3).

The signs of nasal discharge, injected mucosa and pharyngeal discharge are displayed in percentages and the mean values (\pm SD) of any and overall

Table 7. Patient's opinion and appreciation on the study drugs (POD) for D/N and ADM.

| POD score | D/N (59) % | ADM/P (60) % | P-value |
|----------------------|---------------|-----------------|---------|
| Convenience | | | |
| 1 | 6.8 | 6.7 | |
| 2 | 16.9 | 45.0 | |
| 3 | 76.3 | 48.3 | |
| 4 | 0.0 | 0.0 | |
| Mean (SD) | 2.69 (0.59) | 2.42 (0.62) | 0.004 |
| Flavour | | | |
| 1 | 6.8 | 23.3 | |
| 2 | 30.5 | 48.3 | |
| 3 | 47.5 | 28.3 | |
| 4 | 15.3 | 0.0 | |
| Mean (SD) | 2.71 (0.81) | 2.05 (0.72) | < 0.001 |
| Effectiveness | | | |
| 1 | 11.9 | 15.0 | |
| 2 | 22.0 | 33.3 | |
| 3 | 45.8 | 51.7 | |
| 4 | 20.3 | 0.0 | |
| Mean (SD) | 2.75 (0.92) | 2.37 (0.74) | 0.014 |
| Re-using | | | |
| 1 | 13.6 | 18.3 | |
| 2 | 32.2 | 55.0 | |
| 3 | 42.4 | 26.7 | |
| 4 | 11.9 | 0.0 | |
| Mean (SD) | 2.53 (0.88) | 2.08 (0.67) | 0.003 |
| Overall | | | |
| Mean (SD) | 10.68 (2.56) | 8.92 (2.27) | < 0.001 |

sign scores. Table 4 shows that the scores in each and overall signs were significantly decreased in severity from day 1 to day 4 in both treatments ($p < 0.001$). But when comparing the changes of mean score of the overall signs of the D/N group to those of the ADM/P group there was no statistical difference ($p = 0.716$).

The QOL was one of the major objectives of the study, the patients recorded their alertness, freshness and sound sleep after taking the study drugs. Table 5 demonstrates an increase in scores of QOL from day 1 to day 3 in both treatment groups. However, the results showed that there was a statistical difference in QOL between D/N and ADM/P group ($p = 0.024$).

Ninety-six patients (80.7%) in the study had no adverse effects, only 19.3 per cent had either drowsiness or insomnia. Drowsiness was the major complaint of patients in the ADM/P group (23.3%). However, insomnia was the minor complaint in both treatment groups. Table 6 shows that the rate of having

an adverse effect was significantly higher in the ADM/P group than in the D/N group ($p = 0.006$).

POD was evaluated by interviewing the patients at the end of the study on day 4. The percentage of scores in various degrees of all 4 components of POD are demonstrated in Table 7. The means of scores for each POD components were significantly higher in the D/N group than in the ADM/P group especially the flavour of the study drug. In addition, the mean of overall POD scores of the D/N group were statistical significantly higher than that of ADM/P group ($p < 0.001$).

DISCUSSION

Individuals who suffer from common colds usually treat themselves by resting, hot bath and/or steaming water inhalation and adequate water intake. If the symptoms do not improve, they frequently find OTC cold remedies to relieve the symptoms as well as to improve QOL. The patients may go to see the doctor only if the symptoms persist or increase in

severity or are complicated by bacterial invasion. A population-based survey study indicated that 76 per cent of patients with common colds engaged in self care with OTC medications⁽¹⁴⁾.

In the review of clinical trials between 1950 and 1991 on OTC cold medications, Smith & Feldman concluded that no good evidence has demonstrated the effectiveness of OTC medications in children, but certain single OTC medications or combinations have been shown to reduce cold symptoms in adolescents and adults⁽¹⁵⁾. More than 200 cold preparations are available as OTC medication in Thailand. In the present study of 120 patients with the common cold, the authors compared the effectiveness of D/N to ADM/P to control the cold symptoms and to improve the QOL.

From a total of 119 evaluable patients the four most common complaints were cough (47.9%), sore throat (26%), rhinorrhea (8.4%) and headache (8.4%). These findings correspond with Curley et al who found that cough was significant within 24-48 hours of a common cold (83%) and it decreased with time⁽⁷⁾. Although a sore throat is not a characteristic of common colds⁽¹⁶⁾, the authors found that 26 per cent of the patients complained of a sore throat. The authors believe that this complaint is a true sore throat, but represents a burning sensation in the throat which is usually intense within the first 48 hours.

At present, a common cold is considered as a viral rhinosinusitis that often cannot be distinguished from bacterial rhinosinusitis. Gwaltney et al reported the CT findings in 31 patients suffering from the common cold. They found that 87 per cent had abnormalities of one or both maxillary sinuses, 65 per cent had abnormalities of the ethmoid sinuses and 10 per cent and 12 per cent for frontal and sphenoid sinuses respectively. They also stressed that all patients (100%) with symptoms of nasal and head congestion had abnormalities of one or more sinuses and 95 per cent of them had an occlusion of the ethmoid infundibulum. These abnormalities had resolved or markedly improved as much as 79 per cent within 2-week follow-up⁽¹¹⁾. The authors also studied the plain radiographs of the paranasal sinuses in all 119 subjects and found that 26.9 per cent had abnormality of the sinuses. Thickening of maxillary mucoperiosteum and cloudy ethmoid sinuses were most commonly encountered in the presented cases. Despite the findings of sinus abnormalities, these subjects were not excluded from the study, as the authors believed they were viral-caused because there was no evidence of bacterial

invasion. The present findings should remind young physicians on the evaluation of patients with the common cold and they should not rely absolutely on the sinus radiographs, but relate clinically.

In comparison of the efficacy between the two treatment groups, the authors found that all the overall symptoms (Table 3) and sign scores (Table 4) significantly reduced in both groups, but the comparison of the differences of overall symptoms and sign scores between days 1 and 4 from both groups did not reach statistical significance (Table 3, 4). These findings suggested that D/N was as effective as ADM/P in controlling a common cold. Although both treatments shared the same effectiveness, the ADM/P group had more adverse effects especially drowsiness and insomnia (30% in the ADM/P group vs 8.5% in the D/N group, $p = 0.006$) (Table 5).

Some investigators have mentioned liver toxicity in association with Nyquil® in the literature^(17,18). They described three cases of chronic alcoholics who consumed large amounts of Nyquil®. Unfortunately, large amounts of acetaminophen contained in Nyquil® produced hepatotoxicity or even acute hepatic necrosis in those cases.

Many cold preparations produce drowsiness during the daytime because of the antihistamine in those preparations. The patients often fell asleep, lost their freshness, alertness and concentration, which will result in mistakes at work or which studying or even an accident. In contrast, an oral decongestant mixed in the cold remedies may cause palpitation and insomnia at bedtime. Any formulation which makes the patient alert and fresh all day long and sound sleep at night will be a good QOL. The authors surveyed the data from the patients after taking the study drugs and it appeared that the QOL scores of D/N were significantly higher than those of ADM/P ($p = 0.024$).

Lastly, POD was used as an indicator for the patient's thoughts on the drug. The POD scores of D/N and ADM/P were compared, and resulted in a significant appreciation for D/N over ADM/P in all aspects especially the flavour of the drugs ($p < 0.001$) and the decision to reuse the drugs ($p = 0.003$). Recently, Johnson and Drungle reported the factors which encourage people to purchase OTC medications. The older people's decision was based on the product information on the OTC medication package⁽¹⁹⁾. Besides the flavour and convenience people may reuse the OTC medication according to its effectiveness and the product information stating the quantity

of the effective ingredients and the side effects. Manufacturers should improve information on their product in order to benefit the people. Unfortunately, Sangsriy et al, in their 1999 study to evaluate the printed advertisements for OTC product, reported that around 50 per cent of advertisements lacked accurate statements especially on the side effects⁽²⁰⁾. Moreover, pharmacists may play an important role in self-care of the common cold. They can influence the decision to purchase an OTC product, recommend the product and reinforce information regarding the proper use of the drugs⁽²¹⁾.

SUMMARY

1. The most prominent symptoms of common colds within the first 48 hours are cough (47.9%) and sore throat (26%)

2. The abnormal paranasal sinus radiographs were found in 26.9 per cent (n = 119), and most of them were thickening of the mucoperiosteum in the ethmoid and/or maxillary sinuses.

3. Dayquil/Nyquil are as effective as Actifed DM plus paracetamol in controlling the symptoms and signs of common colds but Actifed DM plus paracetamol has more significant adverse effects (in terms of drowsiness) than those of Dayquil/Nyquil.

4. QOL in terms of alertness, freshness during the daytime and good sleep at night was better from day 1 to day 3 in both treatments, however, comparison between Dayquil/Nyquil and Actifed DM plus paracetamol, the former was significantly better than the later.

5. For the patient's opinion and appreciation on the study drugs, the patients preferred Dayquil/Nyquil over Actifed DM plus paracetamol with statistical significance.

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การรักษาโรคหวัด

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ความเป็นมา : การรักษาโรคหวัดโดยมากเป็นการรักษาด้วยตนเอง โดยผู้ป่วยซื้อยาแก้หวัดที่มีขายตามร้านขายยา มารับประทาน ซึ่งยาระงับอาการไอและยาแก้หวัดหลายขนานสามารถซื้อหาได้โดยไม่ต้องมีใบสั่งแพทย์ ผู้รายงานได้ทำการ ศึกษาเปรียบเทียบประสิทธิภาพ, อาการแทรกซ้อน, คุณภาพของชีวิต และความคิดเห็นของผู้ป่วยต่อยาแก้หวัด ระหว่างยา Dayquil/Nyquil และยา Actifed DM ร่วมกับยา paracetamol

วิธีการศึกษา : การศึกษานี้เป็นการทดลองทางคลินิก โดยผู้ทดลองไม่ทราบชนิดของยา ในผู้ป่วยจำนวน 120 ราย อายุระหว่าง 15-60 ปี ที่เป็นโรคไข้หวัดภายในช่วงเวลา 72 ชั่วโมงแรก และผู้ป่วยต้องยอมรับการศึกษาและลงนามไว้

ผู้ป่วยทั้งหมดแยกออกเป็น 2 กลุ่มเท่า ๆ กันแบบลุ่ม มีผู้ป่วย 1 รายถูกคัดออกจากการศึกษาเพราะมีการติดเชื้อ แบคทีเรีย ซึ่งเหลือผู้ป่วยทั้งสิ้น 119 ราย เป็นผู้ป่วยในกลุ่มที่รักษาด้วย Dayquil/Nyquil (D/N) 59 ราย และกลุ่มที่รักษาด้วย Actifed DM และ paracetamol (ADM/P) 60 ราย

ในวันแรกที่เข้ารับการศึกษา ผู้ทดลองจะบันทึกข้อมูลเกี่ยวกับผู้ป่วย (เพศ, อายุ, น้ำหนักตัว, ความดันโลหิต, โรคที่เป็นร่วมด้วย, การใช้ยาต่าง ๆ และการแพ้ยา) อาการที่เด่นที่สุดและระยะเวลาของโรค ผู้ป่วยทั้งหมดจะได้รับการคัดกรองว่า ไม่มีการติดเชื้อแบคทีเรีย โดยการตรวจร่างกาย การตรวจเม็ดเลือด และภาพรังสีของไซนัส ผู้ทดลองจะบันทึกอาการของการ เจ็บป่วยต่าง ๆ (คัดจมูก, น้ำมูก, จาม, ไอ, เจ็บคอ, ไข้และปวดศีรษะ) และอาการแสดงที่ตรวจพบ (การแดงของเยื่อจมูก, น้ำมูกและเสมหะ) และให้เป็นคะแนนแบ่งเป็น 4 ชั้น ตามความรุนแรง (0-3) ในวันที่ 1 และวันที่ 4 ของการศึกษา ผู้ป่วยจะ บันทึกการเปลี่ยนแปลงของอาการ และคุณภาพของชีวิตในแต่ละวันลงในแผ่นบันทึกประจำวัน และผู้ป่วยให้ความคิดเห็นต่อ ยาในวันที่ 4 ของการศึกษา นำข้อมูลการรักษาด้วยยาทั้ง 2 ชนิดมาเปรียบเทียบกับในแง่ของประสิทธิภาพในการลดอาการ และอาการแสดง คุณภาพชีวิต และความคิดของผู้ป่วยต่อยา

ผลการศึกษา : ข้อมูลส่วนตัวของผู้ป่วยทั้ง 2 กลุ่มคล้ายคลึงกัน อาการเด่นของผู้ป่วยที่เป็นโรคหวัดที่พบบ่อย 4 อาการแรก ได้แก่ ไอ (47.9%), เจ็บคอ (26.17%), น้ำมูก(8.4%) และปวดศีรษะ(8.4%) ประสิทธิภาพในการรักษาโรคหวัด ของยาทั้งกลุ่มไม่แตกต่างกัน ในการลดอาการ ($p = 0.426$) และลดอาการแสดง ($p = 0.716$) จากวันที่ 1 ถึง 4 แต่พบว่า ผลแทรกซ้อนของกลุ่ม ADM/P สูงกว่าในกลุ่ม D/N อย่างมีนัยสำคัญ ($p = 0.006$) ในทางตรงกันข้าม คุณภาพของชีวิต ในแง่ของความฉับไวตื่นตัวในการทำงาน ความสดชื่นและการนอนหลับสบาย ดีขึ้นในทั้ง 2 กลุ่ม แต่เฉพาะคะแนนรวมในวันที่ 3 ของกลุ่ม D/N สูงกว่าของกลุ่ม ADM/P อย่างมีนัยสำคัญ ($1.85 \pm 1.83; 1.25 \pm 1.94 : p = 0.024$) ส่วนความคิดเห็นของ ผู้ป่วยต่อยา ในแง่ของความสะดวกสบายในการใช้ รสชาติ ประสิทธิภาพ และความต้องการใช้ในคราวต่อ ๆ ไป ซึ่งผู้ป่วยให้ ความเห็นไว้ในวันที่ 4 พบว่า คะแนนของกลุ่ม D/N สูงกว่ากลุ่ม ADM/P อย่างมีนัยสำคัญ ($10.68 \pm 2.56; 8.92 \pm 2.27; p < 0.001$)

สรุป : ยา Dayquil/Nyquil มีประสิทธิภาพดีพอ ๆ กับยา Actifed DM ร่วมกับยา paracetamol ในการรักษาอาการ และอาการแสดงของหวัด แต่มีอาการแทรกซ้อนน้อยกว่า คุณภาพชีวิตของผู้ป่วยกลุ่มที่ใช้ยา Dayquil/Nyquil ดีกว่า กลุ่มที่ใช้ยา Actifed DM/paracetamol และความเห็นของผู้ป่วยต่อยา Dayquil/Nyquil ดีกว่ายา Actifed DM/paracetamol

คำสำคัญ : โรคหวัด, โพรพามกอกัสเซน, การรักษาทางยา, การติดเชื้อไวรัส

ภาคภูมิ สุปิยพันธุ์, วีระชัย ศิริกาญจนะรงค์,

สุพินดา แสงพานิชย์, อำนวย คัจฉาวรี

จดหมายเหตุมหาแพทย ๙ 2546; 86 (ฉบับพิเศษ 2): S362-S372