Evaluation of "Bronchial Asthma Pharmaceutical Care Clinic for Outpatients" Run by Pharmacists at Nagoya University Hospital

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As many asthma patients suffer from asthma for long periods of time, we considered what pharmacists can do to help them lead a life free of asthma attacks in which they have a high QOL and autonomy.

With this in mind, we established Japan’s first "Asthma Pharmaceutical Care Clinic for Outpatients". Our subjects for counseling at the clinic were new patients with bronchial asthma who were scheduled to begin treatment using a metered dose inhaler or dry powdered inhaler and patients who were undergoing treatment but in whom there had been no improvement in symptoms. At the clinic, the pharmacist identifies problems in the inhalation treatment by questioning the patient and based on the responses, provides instruction on the proper use inhalers so that such problems are avoided.

More than 70% of the 116 patients who visited our pharmaceutical care clinic between July 2001 and March 2004 did not understand what asthma is, or why it is treated with an inhaler. In addition, they were not using inhalers correctly. Initial counseling significantly increased their level of understanding and it was further increased through repeated counseling. Our counseling maintained PEF scores at high levels for over two years.

The counseling pharmacists provided at the bronchial asthma pharmaceutical care clinic for outpatients not only ensured that patients were following the proper inhalation technique, it also gave them useful information on the pathophysiology of asthma and the pharmacology and toxicity of the medicines they use. We are convinced of its effectiveness and necessity.

\textbf{Key words} — bronchial asthma, pharmaceutical care clinic, steroid, $\beta_2$ receptor stimulator, metered dose inhaler (MDI), dry powdered inhaler (DPI)

Introduction

Asthma is internationally recognized as a chronic inflammatory disease by the Global Initiative for Asthma (GINA) working group\textsuperscript{[4]}. Prevention and management guidelines recommend as follows: 1) Asthma and the severity of symptoms be diagnosed in the early stages\textsuperscript{[3]}. 2) A phased drug therapy on the anti-inflammation be continued based on the guidelines\textsuperscript{[3]}. 3) The target of treatment and management programs be clarified, and revalued\textsuperscript{[3]}. If the undervaluation, underestimated treatment, and patient’s ignorance could be evaded, a decrease in asthma deaths and improvement of patient’s QOL could be expected\textsuperscript{[3]}

The Japanese annual report of the Ministry of Health, Labour and Welfare on the movement of the population in 2003 counted the number of asthma deaths according to cause of death at 3,701. A nationwide survey of asthma patients by telephone was conducted in September, 2000\textsuperscript{[7]}. The rates of absence from the work or school and visiting emergency hospital are higher in Japan than European countries\textsuperscript{[6]}. The mortality rate due to asthma is higher in Japan than Europe and America, and asthma is big social problem\textsuperscript{[6]}. Many people are absent from the school and the company due to asthma. Since a peak flow (PEF) meter and the inhaled steroids indispensable to patient’s self management is not so widespread use, the situation of the asthma treatment and management in Japan is worse than that of European countries.

The metered dose inhaler (MDI) and dry powdered inhaler (DPI), which are indispensable to treat asthma, are widely used in the field of respiratory medicine, since they are easily used and carried. In the asthma treatment, the therapeutic outcome is greatly influenced by the amount of
the inhaled medicine to adhere to lungs. Inhaled steroids provide excellent control of local inflammation, and little influence the body overall. Inhaled steroids are the most effective asthma preparation at present, since the use of inhaled steroids has been demonstrated to reduce the frequency of hospitalization and death from asthma attack\(^4\). When the inhalation operation is improper, however an enough effect cannot be expected. Therefore, a positive approach is needed for proper use for the inhalation medicine. We have established “Pharmaceutical Care Clinic of Bronchial Asthma Inhalation Treatment for Outpatient” by the pharmacist in July, 2001, after it was consulted with the department of respiratory medicine. Pharmaceutical care clinic is different from the group type counseling and is the first case in Japan. The pharmacist finds out the problem of inhalation treatment of asthma from an individual patient by questioning like the doctor’s examination, and give a suitable counseling for proper use of medicine in the patient.

In this study, we were able to understand the realities of the asthma treatment, and to contribute to the improvement of therapeutic outcome of asthmatic patients through the counseling.

**Methods**

1. *Subjects*

   The inhalation treatment counseling goes at any time every day. New bronchial asthma patients who were scheduled to receive the inhalation treatment by MDI and DPI, or the patients under the treatment, but had no improvement of the symptom of the bronchial asthma, were targeted in the counseling. Counseling request form was issued by their doctor, and the counseling of inhalation therapy was performed in the counseling room of pharmacy department. The number of patients who had visited the pharmaceutical care clinic between July, 2001 and March, 2004, was 116 (54 male and 62 females), average age 58.16 years old (average±standard deviation), average period of contraction was 18±18 years, average PEF was 68.7±18.1% of standard PEF. In this study, we gave the inhalation counseling, and evaluated the outcome of counseling in 56 patients, who have already received the inhaled steroids, when they have visited the pharmaceutical care clinic.

2. Evaluation of outcome of inhalation counseling

   Nine large items were set up as an evaluation item to the asthma treatment (see Fig. 1). The inhalation counseling evaluation table was prepared. To evaluate basic understanding of patients, the knowledge about [1] the pathophysiology of asthma (two details: chronic inflammatory disease, and controller and reliever), [2] the PEF meters (eight details: the utility, time of use, horizontally, breath-in deeply, firmly holds in the mouth, breath-out strongly, repeated 3 times, and wash up), [3] the asthma diaries (six details: the utility, PEF recording, symptoms, medicines, number of inhale, and exchange day), [4] environmental considerations in daily life (eight details: airway infection, allergen, stress, airway stimulators, antipyretics and analgesic, exercise, alcohol, and occupational asthma), was examined. Moreover, as to understanding to the treatment, the knowledge about [5] the inhaled steroids (five details: see Fig. 2A) and [6] the inhaled \(\beta\) receptor stimulator (six details: see Fig. 2B), was examined. In addition, as to understanding to the inhalation technique, the knowledge about [7] the MDI inhalation without assistance tools (nine details: see Fig. 3A), [8] the MDI inhalation with assistance tools (12 details: see Fig. 3B), and [9] the DPI inhalation (12 details: see Fig. 4) was examined. Each item was scored by 3 stages of 0, 1, and 2 points. When patient understood well and there was no problem, 2 points were given, when patient did not understand there was problem, 0 point was given, when the case was vague, 1 point was given. The full score of each item is 100%. Each point represents the level of patient’s understanding level. A large value (extend to the outside) means patient’s understanding level is high, and the problem is few.

   In addition, 42 patients mentioned above were given the PEF meter to objectively evaluate their clinical conditions, and recording of the asthma diary was counseled.

3. Counseling bronchial asthma inhalation treatment

   At the first visit of the pharmaceutical care clinic, patient’s inhalation technique was evaluated. At the 2rd visit, patients were counseled to improve the patient’s problem, found at the first visit, by using ”Inhalation treatment handbook”. The cause of ineffectiveness of the inhalation treatment, such as poor inhalation technique etc. has been improved as promptly as possible. At the 3rd visit, patient’s inhalation technique was evaluated again, and consulted to improve the remaining worse points. The fourth visit and so on were set as needed. The observation was continued by using the inhalation counseling evaluation table, the PEF meter, and the asthma diary. We investigated whether patient’s inhalation technique had been kept for a long term, and whether the asthma symptoms were under control. Each counseling was performed according to patient’s state and the level of understanding, although it took about 30 minutes.

**Results and Discussion**

1. The level of understanding of patients on the pathophysiology and treatment of asthma before and after counseling of inhalation therapy

   Fig. 1 showed the level of understanding in patients to the pathophysiology and treatment of asthma before and after counseling of inhalation therapy. Before counseling, we found 5 big problems: [1] patients did not understand own disease, [2] patients did not understand why PEF is important, [3] patients did not write asthma diary, [4] patients did not understand own medicine for asthma control, [5], [8], [9] patient did not have proper inhalation tech-
Fig. 1. Evaluation of Patient’s Comprehension to Medical Treatment of Asthma before and after Counseling.

Fig. 2. Evaluation of Patient’s Comprehension to Medicine before and after Counseling.
Each item represents (A1) Products names, (A2) Drug effects, (A3) Dose, (A4) Maximum number of puffs/cylinder, (A5) Adverse drug effects, (B1) Products names, (B2) Drug effects, (B3) Dose, (B4) Timing of inhalation, (B5) Maximum number of puffs/cylinder, (B6) Adverse drug effects, respectively. The full score of each item is 100%. Each point represents the level of understanding. The patients with the high values show high level of understanding (It is satisfactory). *P<0.05, *P<0.01 vs before counseling (paired t-test).

Fig. 2 showed the level of understanding in patients to the medicine to treat asthma before and after counseling of inhalation therapy. The pharmacological effects of inhaled ster-
oids and inhaled $\beta_2$ receptor stimulants were misunderstood by 70% or more of the patients. Almost all of these patients recognized that the inhaled $\beta_2$ receptor stimulants but not inhaled steroid played important role in the treatment of asthma, since they quickly and easily released from breath difficulty at the attack in comparison with inhaled steroids.

Therefore, 16 out of 56 patients were non-adherence for the inhaled steroids and used inhaled $\beta_2$ receptor stimulants only at the attack. These findings suggest that it is important to counsel "What is asthma?" and "Why should use both inhaled medicines?". After counseling, the level of understanding was significantly increased, being increased more completely by repeated counseling. The patient’s self management by PEF is necessary and effective to prevent asthma attack\textsuperscript{10,11}, whereas outpatients did not understand the importance of PEF. Thus, it is more difficult to solve this problem when the asthma symptoms were well control, and there are many patients who appealed that the recording the asthma diary was troublesome [3]. It is suggested that the counseling is necessary how to use the PEF meter and diary for self management of asthma. Moreover, it is also important to know the background of patient’s life, to prevent the cold, to make the rule for the coexistence with pet, to do environmental maintenance, and to counsel the first prevention of the asthma attack.

Fig. 3. Problems of Patients in MDI Inhalation before and after Counseling.
Each item represents (A1) Shake the cylinder well, (A2) Keep distance between mouth and mouth piece (3–4 cm), (A3) Exhale with abdominal type of respiration, (A4) Open the throat, (A5) Inhale slowly and deeply, (A6) Hold breath (5–10 sec.), (A7) Exhale with abdominal type of respiration, (A8) Rinse mouth, (A9) Open regular intervals, (B1) Install mouthpiece, (B2) Shake the cylinder well, (B3) Exhale with abdominal type of respiration, (B4) Open the throat, (B5) Hold the mouthpiece in the mouth, (B6) Puff to direction, (B7) Inhale slowly and deeply, (B8) Hold breath (5–10 sec.), (B9) Exhale with abdominal type of respiration, (B10) Rinse mouth, (B11) Open regular intervals, (B12) Wash the aid, respectively. The full score of each item is 100%. Each point represents the level of understanding. The patients with the high values show high level of understanding (It is satisfactory). $^aP<0.05$, $^*P<0.01$ vs before counseling (paired t-test).

Fig. 4. Problems of Patients in DPI Inhalation before and after Counseling.
Each item represents (1) Install inhaler, (2) Keep inhalation port clean, (3) Open the hall on disk, (4) Keep the inhaler horizontal, (5) Exhale with abdominal type of respiration, (6) Open the throat, (7) Hold the mouthpiece in the mouth, (8) Breath in strongly and deeply, (9) Hold breath (5–10 sec.), (10) Exhale with abdominal type of respiration, (11) Rinse mouth, (12) Clean up the inhaler, respectively. The full score of each item is 100%. Each point represents the level of understanding. The patients with the high values show high level of understanding (It is satisfactory). $^aP<0.05$, $^*P<0.01$ vs before counseling (paired t-test).
2. The level of understanding of patients on the inhalation technique before and after counseling of inhalation therapy

Fig. 3 showed the problems when the patients operated the MDI inhalation, and fig. 4 showed the problems when the patients operated the DPI inhalation, before and after counseling of inhalation therapy. Fig. 3 A showed the case of open mouth method of inhalation (without inhalation assistance tool), and fig. 3 B showed the case to use the inhalation assistance tool. Almost patients did not have the correct inhalation technique before counseling at the case of open mouth method of inhalation. In both cases of MDI and DPI, patients did not have the basic technique. They could not behave as follows: breath out enough before inhalation by abdominal type respiration, inhale deeply from the mouth, hold breath, breathe out slowly again by abdominal type respiration. Therefore, we thoroughly practiced these four basic techniques to the patient. After counseling once, these were improved, but not enough. It is suggested that repeated counseling and cross-checks are necessary to improve and maintain the proper inhalation techniques. Since there are many patients who use inhaled β2-receptor stimulants at the asthma attack without any assistance tool, the effect of the medicine may not enough, and lead to excessive use. It has been reported when the inhalation assistance tool are used: 1) the amount of the medicine adheres to the bronchial tract is able to increase, 2) the amount of the medicine to the mouth and the pharynx that causes the side effect is able to decrease, 3) the amount of the medicine to the mouth and the pharynx that causes the side effect is able to decrease, compared with the case without any inhalation assistance tools. We recommended to stop to inhale by open mouth method (without assistance tool) to patients. The inhalation assistance tool was offered to patient free of charge. Counseling was repeated to teach a proper inhalation technique to the patients with an inhalation assistance tool as much as possible.

3. PEF value in patients before and after counseling of inhalation therapy

The PEF value of the patients before counseling the inhalation therapy was defined as 100%. The average PEF (± standard deviation) values were 107.6±5.6% (n=42), 108.3±4.2% (P<0.05, n=42), 108.6±4.4% (P<0.05, n=42), 108.3±5.1% (P<0.05, n=35), and 107.9±5.8% (P<0.05, n=15) at 1, 3, 6, 12 and 24 months, respectively, after counseling. Excellent PEF value in the asthma patients was significantly maintained over a long-term by counseling although 42 patients have the history of chronic asthma of 21 years on the average (paired t-test).

There are various styles of asthma educations for patients. In general, the physicians educate the asthma patient at examination, consults the future treatment, explain the prescribed inhalation medicine. The examination period of the respiratory tract medicine for our hospital is 15 minutes on the average. It is necessary to prepare the inhaler for the training in each examination room to do the inhalation practice. On the treatment of the bronchial asthma, it is insufficient only the drug therapy and it is necessary to notice various environmental problems that surround the patient. The effective and early preventive guidance of the respiratory infections is indispensable. In many cases, the nurse should do the life guidance of the patient. Actually, the life guidance is not done spending enough time. In this study, the results of before counseling suggest that the patient educations dose not go well. At first, the classroom of the bronchial asthma treatment was examined. Making the best practice of the physician, the nurse, and the pharmacist each specialty, the group counseling was planned for two or more patients. The classroom is seen to be unfavorable for the patients because they are restrained several hours in the hospital on non-examination day, and a necessary level for an individual patient is too different. From these reasons, we concluded the conventional group guidance is insufficient and inefficient way in the education of asthma patients.

In the pharmaceutical care clinic, pharmacist can make the best use of pharmacist’s expertise of inhalation medicine, pharmacist can guide patients in the importance of the inhalation steroid in the bronchial asthma treatment, in the safety of the inhalation steroid, in monitoring of the side effect, and in the proper using with the bronchial dilator. In addition, a lot of inhalation materials are kept in the counseling room. A pharmacist who know how to use these inhalers very well, do the demonstration of inhale personally, the guidance of proper and effective inhalation becomes possible.

Patients say that they will not have heard the explanation of which they can consent. Many of patients who have already used the inhaler are surprised at the difference with the inhalation that they had done up to now. The physician in the respiratory internal medicine actually feels the therapeutic gain of the patient education. They say that hospital can take the addition for education of asthma patients in a dignified manner. Of course, it is necessary to manage by the PEF meter to obtain the additional fee. It is important for preventing the asthma death to educating the initial action plan to the asthma attack by using the asthma diary.

To our regret, the pharmaceutical care clinic for pediatric asthmatic patients is not done, and it is making arrangements with pediatric department now. The specialist of asthma say that the inhalation guidance is very possible for a child of six years old or more and that guidance to the parents is also more important for the pediatrics than adults.

The qualities of patient education should be equivalent on the outpatient and the inpatient. Three concurrently pharmacist can do the inhalation guidance now, and support each other. One pharmacist take charge of the outpatient, and another two pharmacists of the ward of respiratory internal medicine take charge of the inpatients of all hospital wards.

Through the patient counseling at the pharmaceutical care clinic of bronchial asthma inhalation treatment for outpatient by pharmacists, the patients were able to get not only a proper inhalation techniques, but also accurate knowledge of
pathophysiology of asthma and pharmacology and toxicity of medicines. After the patients got the inhalation techniques, a significant increase of the peak flow rate was observed. To keep the level of understanding in patients, the level should be repeatedly confirmed, and counseling. According to the report of the nationwide asthma patient telephone investigation in Japan\(^1\), 75% of the patients got information from their physicians, and 4% from other co-medical workers, whereas 96% of patients were not satisfied with the information.

It is indispensable to establish the partnership among the physician, the nurse, the pharmacist, and the patient to keep steady self management of asthma and to improve QOL in patients\(^{13,14}\). For this purpose, it is necessary to offer the treatment plan and the self management method according to individual patient’s character, life style, and family situation, etc. We have a trust that pharmacist sure can support asthma patients by counseling at pharmaceutical care clinic in the proper inhalation medication. Asthma patients who are struggling with asthma so long time, can enjoy the life without asthma attack, with high QOL and autonomy.

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