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Original article

Caregiver treatment satisfaction is improved together with children's asthma control: Prospective study for budesonide monotherapy in school-aged children with uncontrolled asthma symptoms

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Abbreviations:
ICS, inhaled corticosteroid; CTS, caregiver treatment satisfaction; JPAC, Pediatric Asthma Control Program; QoL, quality of life; BUD-TBH, budesonide Turbuhaler®; LTRA, leukotriene receptor antagonist; % FEV_1, forced expiratory volume in 1 second percent predicted; %PEF, peak expiratory flow percent predicted; %MMF, maximum mid-expiratory flow rate percent predicted

ABSTRACT

Background: If asthmatic children cannot obtain sufficient control of their disease, not only do they suffer from asthma symptoms, but the daily life activities of their caregivers are also disrupted. We investigated the effectiveness of an inhaled corticosteroid (ICS) for symptom control in previously ICS-untreated school-aged asthmatic children as well as caregiver treatment satisfaction (CTS).
Methods: A multicenter, open-label, single-arm study on 12-week ICS (budesonide Turbuhaler®) monotherapy was undertaken in subjects aged 5–15 years with bronchial asthma not treated with ICS during the previous 3 months. At 0, 4, 8, and 12 weeks after start of ICS administration, Japanese Pediatric Asthma Control Program (JPAC) scores, and CTS scores were summated and lung function measured. At weeks 0 and 12, questionnaires on caregiver anxiety were also assessed.
Results: Seventy-five patients were enrolled, and 69 assessed. Ninety percent of subjects had been treated with asthma controller medication except ICS before study enrollment. JPAC score and CTS score were improved significantly at weeks 4, 8, and 12 ($p < 0.001$). With regard to CTS, more than half of caregivers showed a perfect score at weeks 8 and 12. There was a significant correlation between JPAC score and CTS score. Lung function and caregiver anxiety were also improved, and good compliance with treatment was observed during the intervention.
Conclusions: If treating ICS-untreated school-aged asthmatic children with uncontrolled symptoms, ICS monotherapy can improve CTS along with improving asthma control.

Introduction

If asthmatic children cannot obtain sufficient control of their disease, not only do they suffer from asthma symptoms, but the

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daily activities of life of their caregivers are also disrupted. A report on a questionnaire developed to assess the quality of life (QoL) of caregivers of asthma patients[1] showed that caregiver QoL was correlated with asthma control in children.[2] Whether caregivers feel confident and are satisfied with a child's asthma treatment is an important factor influencing the success or failure of treatment because the assistance of caregivers is essential for long-term management of asthma.[3]

Inhaled corticosteroids (ICSs) are the first-line treatment of asthma for school-aged and older patients.[4] In Japan over the past decade, ICSs have been prescribed more commonly, but the prevalence of prescription of ICSs in asthmatic children remains low[5] (presumably because of anxiety regarding their side effects[6]). Thus, a non-negligible number of asthmatic children are thought to suffer from insufficient control of asthma. ICS administration is likely to improve the asthma control and lung function of patients, as well as caregiver treatment satisfaction (CTS). Several studies have shown the effectiveness of ICS for the treatment of childhood asthma.[7] However, prospective studies in children with uncontrolled asthma focusing on asthma control and CTS in ICS monotherapy are lacking.

We conducted a 12-week prospective study with budesonide Turbuhaler® (BUD-TBH) monotherapy to elucidate the effectiveness of ICS monotherapy in asthmatic children who did not use an ICS in the previous 3 months, and in whom previous treatment did not enable sufficient control of asthma. Asthma control by patients was measured using the Japanese Pediatric Asthma Control Program (JPAC) score.[8,9] The relationship between CTS and symptom control by patients was also assessed.

Methods

The present study (UMIN000005155) was conducted in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the Ethical Review Board of Dokkyo Medical University (Tochigi, Japan).

This was a multicenter, open-label, single-arm study to evaluate symptomatic improvement, influence on CTS, and safety after 12 weeks of switching to ICS (BUD-TBH) monotherapy in subjects aged 5–15 years with bronchial asthma who had not used an ICS in the previous 3 months. It was conducted between March 2011 and June 2012 at participating institutes.

Subjects

Subjects were enrolled if they satisfied all of the following inclusion criteria: written informed consent could be obtained from the patient and parents/guardians (for patients who were too young to provide written informed consent, verbal assent of the patients confirmed by a parent/guardian could be substituted); outpatients with bronchial asthma aged 5–15 years; patients who were ICS-naïve or not treated during the preceding 3 months; patients who were diagnosed with poorly controlled asthma based on the JPAC questionnaire[8,9] upon study enrollment; patients who could schedule four visits with same guardian.

Patients were excluded from the study if they: had received systemic corticosteroid therapy within the preceding month; could not use the Turbuhaler® appropriately (as judged by the investigating physician); were contraindicated for the study drug; had any chronic respiratory disease other than asthma; had an acute infection of the lower respiratory tract upon study enrollment; were judged by the investigating physician to be inappropriate for this study.

Treatment and measurements

Subjects were treated with BUD-TBH (400 μg/day) for 12 weeks. Any other controller medications were discontinued before study commencement.

The JPAC score (range, 0–15) was scored as: 15 points, complete control; 12–14, favorable (insufficient) control; and ≤11, poor control. CTS using a "face scale"[10,11] (five grades scored from 1, extremely dissatisfied to 5, extremely satisfied) designed originally for this study (Fig. 1), spirometry and patient-reported adherence of inhalation (five grades: almost 100%; nearly 75%; nearly 50%; nearly 25%; almost did not) were measured 0, 4, 8, and 12 weeks after the start of ICS administration. Allowance for deviation from a scheduled visit date was set as ±14 days. Standard values of spirometry parameters were calculated using standard formulae provided by the Japanese Society of Pediatric Pulmonology.[12] At week 0 and week 12, a questionnaire on caregiver anxiety was also assessed. The questionnaire contained 14 questions designed originally for this study based on a previous QoL report.[1] Answers were "yes" or "no" and multiple responses were allowed (Table 1). CTS and caregiver anxiety questionnaire constraints had to be answered by the same caregiver.

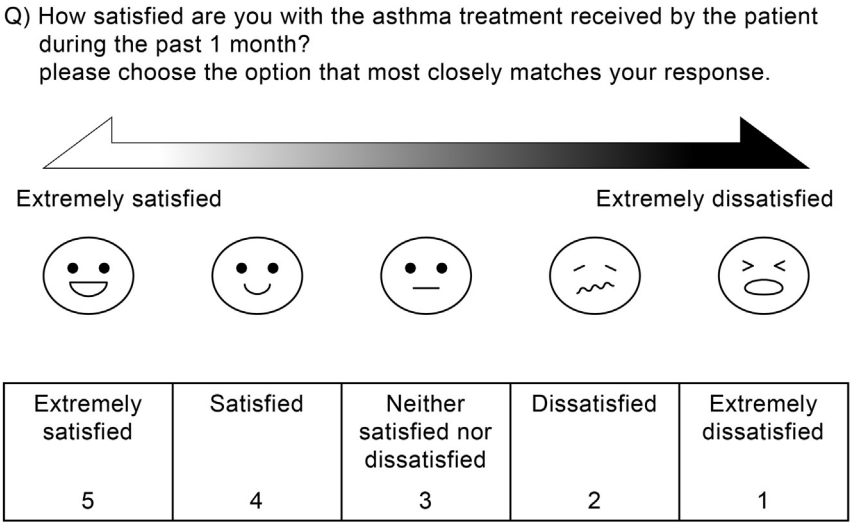

Fig. 1. Caregiver treatment satisfaction (CTS) questionnaire. The face scale has five grades [1 (extremely dissatisfied) to 5 (extremely satisfied)].