ADHERENCE TO INHALED CORTICOSTEROID USE AND LOCAL ADVERSE EVENTS IN PERSISTENT ASTHMA

CONCLUSION: Patient-reported adherence to ICS therapy using both prescription claims and a patient survey; 2) identify local adverse events (LAEs) from the patient perspective and from reports in the medical chart; and 3) evaluate the association between LAEs and adherence to ICS therapy. METHODS: Patients aged 6–64 years with persistent asthma, defined using an established algorithm, and at least 2 ICS prescriptions were selected from a claims database (1999–2005) of a central Massachusetts medical group practice organization. Prescription claims were used to calculate the ICS medication possession ratio (MPR) as the sum of ICS medication days supply over the year after index medication divided by 365. A survey obtained information on patient-reported adherence to ICS therapy by using the Morisky scale and assessed patient-reported LAEs using the validated Inhaled Corticosteroid Questionnaire (ICQ). Medical charts of survey respondents were abstracted for LAEs.

RESULTS: The study sample included 372 survey respondents. Only 2.7% met the claims-based measure of good adherence (a MPR ≥ 80%). Patient-reported adherence was much higher; 20.7% of patients were highly adherent based on Morisky scale (score = 0). Medical chart review identified 27.2% of patients with at least one LAE within a year after ICS index date, but only in 5.6% of patients were LAEs related to ICS use. However, the responses to the ICQ showed that 47% of patients reported being bothered at least “quite a lot” by at least one LAE. Multivariable analyses indicated that unpleasant taste was significantly related to lower adherence based on the Morisky scale (P = 0.0175). CONCLUSION: Patient-reported adherence was higher than claims-based. Patients reported being bothered by LAEs more often than recorded in medical charts. Unpleasant taste appears to be associated with lower adherence based on the Morisky scale.

USE OF INTERACTIVE VOICE RESPONSE (IVR) TO COLLECT DAILY PATIENT DIARY DATA IN A CLINICAL TRIAL OF SEASONAL RHINITIS

OBJECTIVE: Automated IVR telephone-based systems are widely used in many aspects of clinical trials, but there is relatively little empirical data to support the use of IVR for collecting patient reported outcomes (PROs) such as daily symptom diaries. We have evaluated IVR in a placebo-controlled trial of seasonal rhinitis. METHODS: Patients were allocated at random to receive either 200mg budesonide or placebo for three weeks. All patients received up to 120 mg per day terfenadine as required. Patients dialled into an IVR system each evening. Blocked nose, stuffy nose, runny nose, and eye symptoms were rated by pressing a button on the phone keypad to record severity on the scale 0 = absent; 1 = mild; 2 = moderate; 3 = severe. Patients also recorded the number of terfenadine tablets taken. RESULTS: Data were collected from 32 patients (15 male) aged 19–65 years. Patients were able to use the IVR system without difficulty. All four symptoms showed lower average severity over the study period for the budesonide group than for placebo. This was significant for blocked nose (Wilcoxon S = 237, p < 0.01); eye symptoms (S = 218, p < 0.05); overall symptoms (S = 229, p < 0.05). The number of terfenadine tablets taken was also lower in the budesonide group than for placebo (S = 225, p < 0.05). CONCLUSION: These data demonstrate the effects of an established treatment, and suggest that IVR is a valid method for collecting PRO data in an unsupervised environment. The application was relatively simple, involving familiar and easily understood symptoms, and response options that were the same for all symptoms. Further research to investigate more complex PRO applications is warranted.