News Release

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FOR MORE INFORMATION, CONTACT:
Keely Savoie or Brian Kell
ksavoie@thoracic.org or bkell@thoracic.org
ATS Office 212-315-8620 or 212-315-6442 (until May 14)
Cell phones 917-860-5814 or 516-305-9251
ATS Press Room: 504-670-6926 (May 15 to 20)

Press conference time: May 16, 4:30 p.m. in the ATS Press Room (E-1)

Poster session time: 1:30-4:00 p.m. May 17
Location: CC-Room 228-230 (Second Level), Morial Convention Center

Internet Monitoring Strategy for Severe Asthma Patients Shown to be Effective

ATS 2010, NEW ORLEANS— Patients with severe asthma who use an internet-supported strategy and daily monitoring of exhaled nitric oxide (FENO) were able to control their asthma with lower overall dosing of oral corticosteroids (OCS) than patients who underwent usual care, according to research from the Netherlands.

"We know that in patients with prednisone-dependent asthma it is important to adjust the daily dose of oral corticosteroids to the lowest possible level in order to reduce long-term side effects," said Simone Hashimoto, M.D., research fellow from the department of respiratory medicine of the University of Amsterdam. "Our study shows that a novel internet-supported strategy including daily measurements of an objective marker of airway inflammation, FENO, and supervision by an asthma nurse allows frequent adjustments of prednisone dose, and leads to significant reduction of total corticosteroid consumption over a six months study period, as compared with patients receiving usual care. This was not accompanied by deterioration of asthma control or asthma-related quality of life."

The findings were presented at the ATS 2010 International Conference in New Orleans.

People with chronic health conditions, such as severe asthma, require continuous medical supervision, which can often be a logistical challenge, not only for overburdened healthcare systems, but for patients themselves, who may not have the time or flexibility to keep frequent appointments. "Internet monitoring allows centralized continuous long-distance support of patients, which can improve the quality of care, reduce the hazards associated with oral corticosteroids tapering, and can prevent drug-induced morbidity and mortality," explained Dr. Hashimoto.

While it was known that in patients with milder asthma, such programs had shown success, patients with severe asthma had yet been studied.

"Some patients with severe asthma require frequent bursts or even daily use of oral corticosteroids despite treatment with high dose of inhaled asthma medication. This leads to serious long-term adverse effects such as diabetes, blood hypertension, depression and osteoporosis, that may critically affect patients' quality of life and have considerable public health implications," explained Dr. Hashimoto. "Since adverse effects are dose and time dependent, corticosteroids should always be used in the lowest possible dose. In current practice, oral corticosteroid dose adjustments are made periodically by the patient's physician, based on subjective symptoms and signs, and not by objective parameters."

Dr. Hashimoto and colleagues designed a prospective, randomized, parallel, multicenter study with 89 patients with severe asthma study to test the hypothesis that a new internet-based strategy including daily home monitoring of symptoms, lung function, FENO, and regular feedback by an internet asthma nurse, would lead to a significant reduction of corticosteroid consumption without worsening of asthma control or asthma-related quality of life. In total, 89 patients were randomized to two tapering strategies: usual care, or internet-supported with daily monitoring of FENO, FEV1 and symptoms.

For those assigned to the internet-supported strategy, each patient had a password used to log in to a secure site where they recorded daily symptoms, lung function values, FENO value and dose of medicine that they took in the day. The values were controlled every day by a specialized asthma nurse and once a week patients received instructions about the dose of oral corticosteroids they should use. The process took about 5 minutes per day for the patient, and was well accepted. Patients could also contact the asthma nurse via the website or email in the event of questions or problems.

The researchers found that among patients assigned to the internet-supported strategy, cumulative 6-month dosing of OCS was significantly lower. "Of course, we hoped to find a positive result, because internet based self-management and management guidance by FENO has already been proven to be successful in adolescents with milder forms of asthma," said Dr. Hashimoto. "However, we were surprised that also in patients with severe prednisone-dependent asthma this strategy proved to be successful. These patients have years of continuous use of oral corticosteroids and a long history of attempts to taper their maintenance prednisone dose without success. This strategy gives them new hope that they can safely reduce the deleterious long-term side effects of prednisone."

“Our findings suggest that this novel internet-based strategy can and should be applied in all patients with severe prednisone dependent asthma to reduce total corticosteroid consumption. Internet technologies as well as biomarker driven therapies will become more and more common in future health care,” Dr. Hashimoto concluded. “In the future, we will do more studies on a larger scale, to evaluate whether this strategy should be incorporated in guidelines for management of patients with severe asthma.”

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“Monitoring Exhaled Nitric Oxide (FENO) to Tailor the Lowest Effective Dose of Oral Corticosteroids in Sever Asthma (MONOSA- Study)” (Session B92, Monday, May 17, 1:30- 4:00 p.m., CC-Room 228-230 (Second Level), Morial Convention Center; Abstract 492)

**Please note that numbers in this release may differ slightly from those in the abstract. Many of these investigations are ongoing; the release represents the most up-to-date data available at press time.*

Monitoring exhaled nitric oxide (FE_{NO}) to tailor the lowest effective dose of oral corticosteroids in severe asthma (MONOSA-Study)

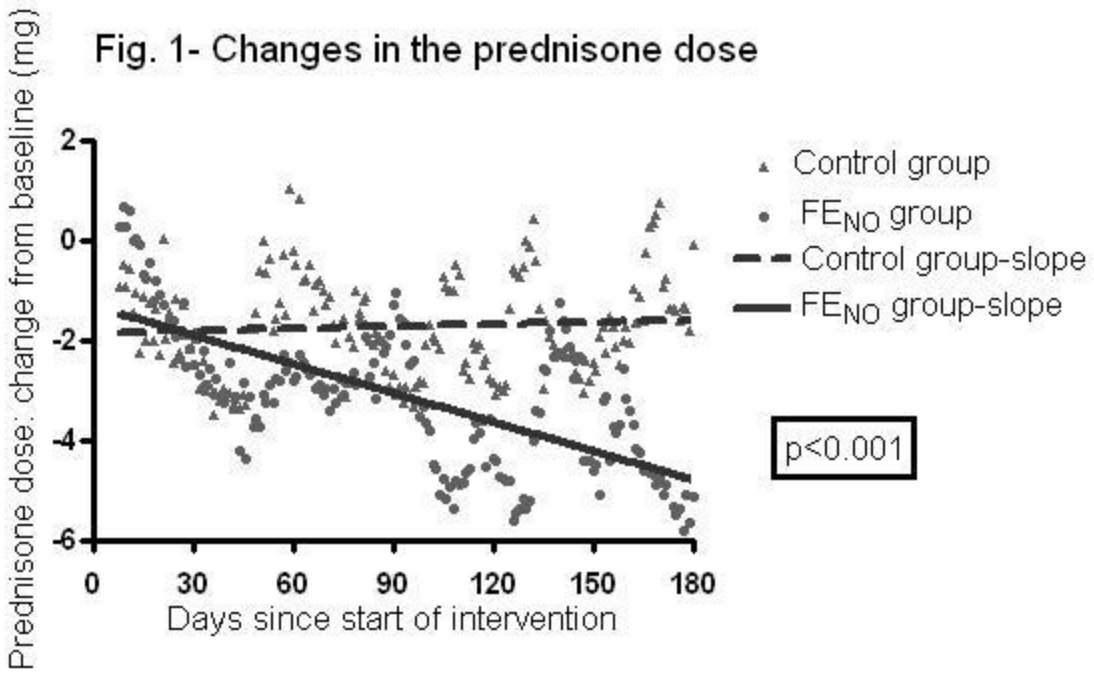
S. Hashimoto[1], A. Ten Brinke[2], A.C. Roldaan[3], I.H. van Veen[4], G.M. Möller[5], J.K. Sont[5], E.J.M. Weersink[1], J.S. Van der Zee[1], A.H. Zwinderman[1], P.J. Sterk[1], E.H. Bel[1]
[1]Academic Medical Center - University of Amsterdam - Amsterdam/NL, [2]Medical Center Leeuwarden - Leeuwarden/NL, [3]Haga Ziekenhuis - Den Haag/NL, [4]Medisch Spectrum Twente - Enschede/NL, [5]Leiden University Medical Center - Leiden/NL

Rationale: In patients with prednisone-dependent asthma it is important to adjust the daily dose of oral steroids (OCS) to the lowest possible level in order to reduce long-term side effects. However, the optimal strategy for tapering OCS in patients with severe asthma is not known. FE_{NO}, a non-invasive marker of airway inflammation, has been used successfully to adjust the dose of inhaled corticosteroids in mild-to-moderate asthma (Smith et al. NEJM 2005)

Hypothesis: Daily monitoring of FE_{NO} in severe asthma facilitates tapering of OCS to the lowest effective dose and leads to a reduction of total corticosteroid consumption without worsening of asthma control (ACQ) or asthma-related quality of life (AQLQ).

Aim/Method: In a 6 months prospective, randomised, parallel, multicenter study 89 patients (mean(SD) age 50.2(12.3); 48 female) with prednisone-dependent asthma were randomised in 2 tapering strategies: according to usual care (n=38) or guided by FE_{NO} (n=51) via an internet based monitoring system. The primary outcomes were cumulative dose of OCS, ACQ (Juniper) and AQLQ(S) (Juniper). Secondary outcomes were FEV_1, number of exacerbations, steroid side effects and patient's satisfaction with the OCS adjustment strategy. Parametric and non-parametric tests and mixed-effects regression models were used in the analysis.

Results: The cumulative spared dose of prednisone over 6 months was significantly higher in the FE_{NO} group (median(range) 205 mg (-2337 to 4037) mg) compared with 0 (-1435 to 2765) mg in the control group, p=0.025. Mean(SD) OCS dose decreased from 13.9 (10) to 9.51 (9) mg/day in the FE_{NO} group as compared to an increase of 11.5 (7.7) to 12.7 (12) mg/day in the usual care group, $p<0.001$(fig.1). Patients had a slightly better (but not clinically relevant) asthma control in the usual care group as compared with the FE_{NO} group (mean(SD) difference in ACQ score of 0.04 (0.02)*vs* 0.34(0.01), p=0.026. There were no significant differences in the AQLQ(S), FEV_1, exacerbations, steroid side effects or rate of satisfaction with the strategy between the study groups.



Conclusion: A strategy based on daily monitoring of FE_{NO} in severe asthma is successful in reducing total corticosteroid consumption without compromising asthma control or asthma-related quality of life.

Implication: Internet based strategies using daily FE_{NO} measurements might become the standard for tapering oral steroids in patients with severe, steroid-dependent asthma.