Assessment of long-term effects of combined extra-fine beclomethasone and formoterol treatment in asthma patients using functional imaging

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Hypothesis: functional imaging (FI) using computer methods can be used to evaluate the additional benefits of extra fine particle formulations in long term steroid treatment of asthmatic patients. Due to the high sensitivity of the FI techniques, FI results could correlate better with clinical outcome compared to lung function tests (LFT).

10 asthmatics (5M/<52y>) were treated with 2 inhalations BID of BECLO(100mug)/FORMO(6mug) Modulite® for 6 months. Patients were either steroid naïve (n=2), partially (n=4) or completely (n=4) controlled under their current fine particle steroid treatment. LFT data and FI data were collected at baseline and after 6m of treatment. An asthma control score (ACS) was assessed to evaluate the clinical outcome.

Results can be found in Table 1.

This study showed that exhaled NO, airway resistance and FI are sensitive measures to detect changes in lung function after 6m of steroid treatment in extra fine particle formulation. In addition parameters such as NO and FI appear to correlate significantly with clinical outcome in contrast to the standard spirometry and bodyplethysmography values. In conclusion, FI proves to be a very sensitive technique to assess changes in lung function while also being a good marker for clinical outcome.

Table 1 #

	lung function change			correlation with ACS	
	baseline	6 months	p	R^2	p
FEV1 [%pred]	97.8	102.88	0.17	0.04	0.60
FEV1 [L]	2.988	3.179	0.17	0.06	0.49
FVC [L]	4.135	4.164	0.61	0.09	0.41
FEV1/FVC [%]	72.133719	75.414391	0.09	0.19	0.21
FRC [L]	3.387	3.246	0.59	0.05	0.52
TLC [L]	6.341	6.431	0.28	0.00	0.85
exNO [ppb]	51.16	15.86	0.05 *	0.44	0.04 *
sRaw [kPas]	1.5684	1.0898	0.01 *	0.11	0.36
iVaw [mm]	43955.963	48272.081	0.005 *	0.47	0.03 *
iRaw [kPas/L]	0.1037047	0.0389163	0.005 *	0.59	0.009 *
ACS	21	23.3	0.12		

Changes in LF and FI parameters after 6m of steroid treatment and the correlation of observed changes in LF with clinical outcome (* for statistical significance)