

PIKO-1, A NOVEL OPPORTUNITY FOR THE PATIENT'S PERSONAL PEFR AND FEV₁ ELECTRONIC MONITORING: A COMPARISON STUDY VS A CONVENTIONAL SPIROMETER

Eur Respiratory Society Annual Congress, Glasgow, Sept. 6, 2004

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Introduction (1)

Subjects with airway obstruction are strongly recommended to monitor their lung function, which is particularly variable in asthma.

The most common indices of forced expiratory flow are FEV_1 , the maximum volume of air expired in 1 second from full inspiration, and PEF, the maximum flow rate that can be generated during a forced expiratory manoeuvre.

Introduction (2)

Although FEV_1 is the single best measure for assessing severity of airflow obstruction, PEF_R is a simple and reproducible measure of airflow obstruction which correlate quite well with that of FEV_1 , and can be measured with inexpensive and portable peak flow meters.

The daily PEF_R and FEV_1 monitoring can be a simple and objective procedure for assessing and monitoring airway obstruction, but actually it is difficult to perform by usual devices.

PIKO-1 (PDS, Ferraris, USA): the claims

- It's the first electronic device for both PEFr and FEV₁ personal check;
- PEFr range = 15 - 999 L/min (resolution 1L/min);
- FEV₁ range = 0.15 – 9.99 L (resolution 0.01 L);
- dimension = 75 x 35 x 20 mm;
- pocket size (35 g weight)
- quality control of respiratory manoeuvres;
- high precision;
- storage up to 96 tests;
- predicted values ATS 1994;
- conformed to EN60601-1-2.

Aim

To compare PEF_R and FEV₁ values from PIKO-1 and those from a conventional spirometer in subjects with airway obstruction.

Methods

- 352 subjects (217 males);
 - mean age = 47.6 years \pm 19.0 sd;
 - mean weight = 72.6 kg \pm 15.0 sd;
 - mean height = 168.1 cm \pm 11.9 sd
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- Each subject performed 3 sequential measures from PIKO-1 and from a conventional spirometer (Masterscreen, Jäger, Germany).

Statistics

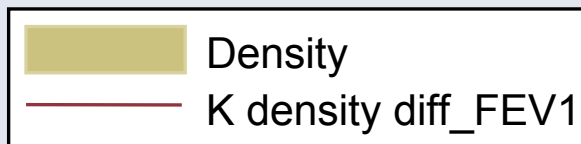
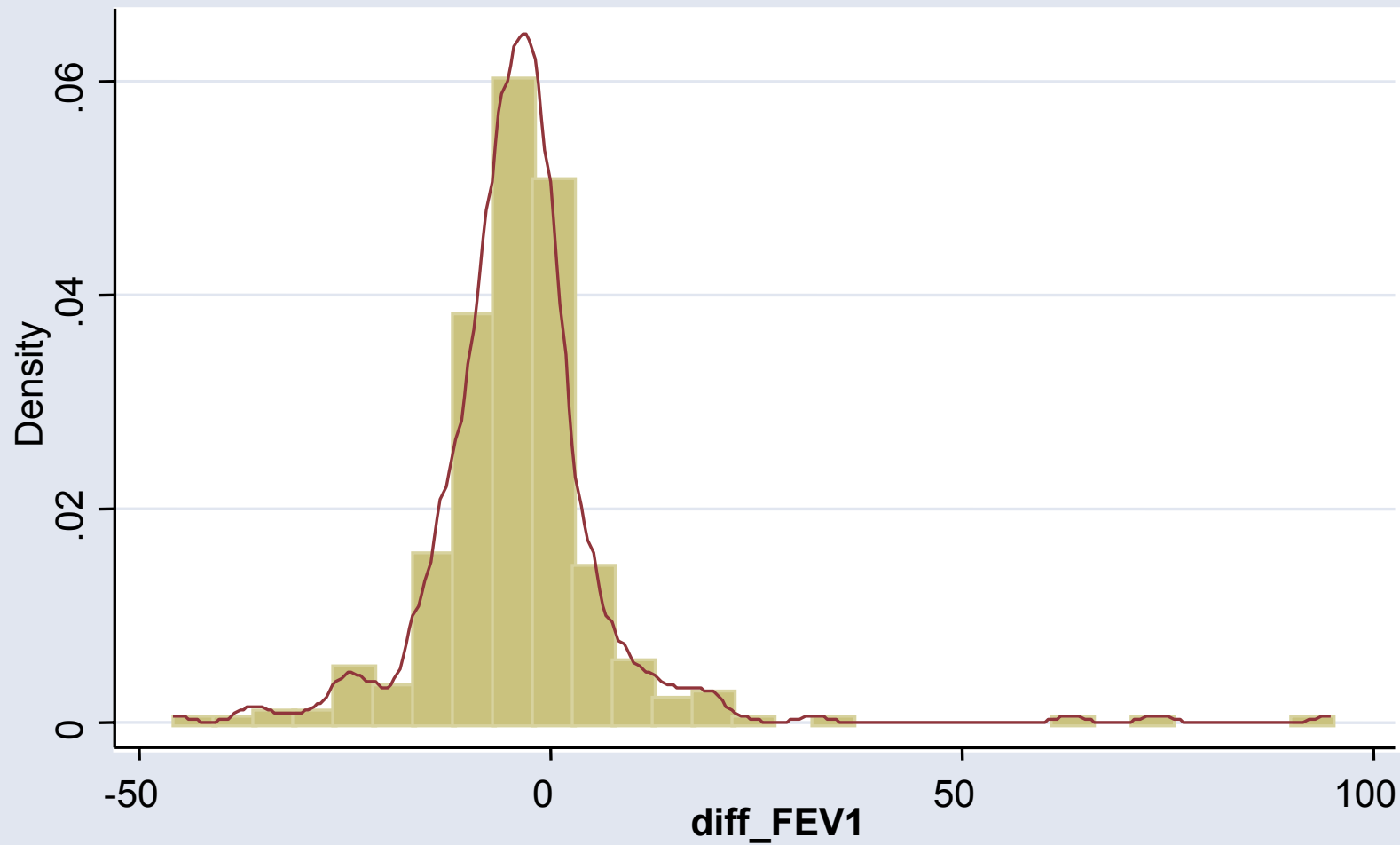
- Wilcoxon signed-rank test;
- Sign test;
- $p < 0.05$ accepted

Results 1:

mean FEV₁

- 2,9 L \pm 1.1 sd from spirometer
- 3.0 L \pm 1.1 sd from PIKO-1

PIKO-1 over-estimated FEV₁ values by 4 % (p < 0.001) systematically



Regressione fev1_sp contro gender, age, height, weight e a_b

Regression with robust standard errors

Number of obs = 346
F(5, 340) = 156.70
Prob > F = 0.0000
R-squared = 0.6791
Root MSE = .6234

fev1_sp	Coef.	Robust Std. Err.	t	P> t	[95% Conf. Interval]	
gender	.3986065	.0971892	4.10	0.000	.2074387	.5897743
age	-.020252	.0020404	-9.93	0.000	-.0242654	-.0162385
weight	.0070038	.0027817	2.52	0.012	.0015323	.0124753
height	.0345781	.0050692	6.82	0.000	.0246071	.0445491
a_b	-.6258472	.1269542	-4.93	0.000	-.8755617	-.3761328
_cons	-2.364896	.7512544	-3.15	0.002	-3.842588	-.8872048

Regressione fev1_sk contro gender, age, height, weight e a_b

Regression with robust standard errors

Number of obs = 346
F(5, 340) = 147.12
Prob > F = 0.0000
R-squared = 0.6663
Root MSE = .64637

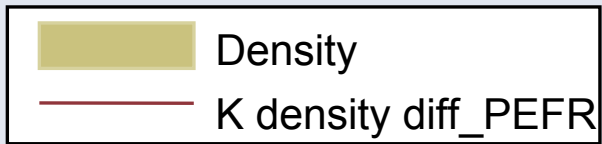
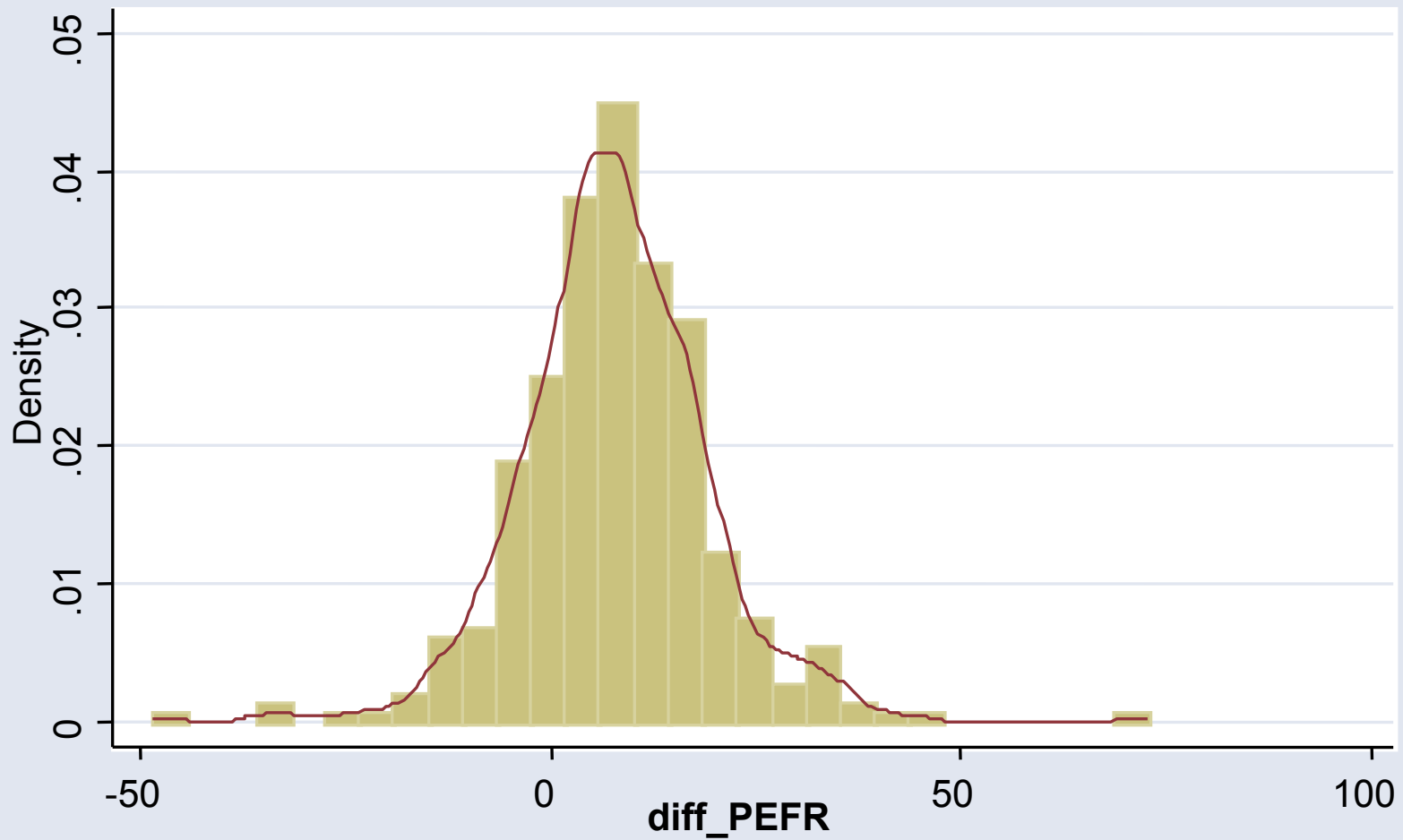
fev1_pk	Coef.	Robust Std. Err.	t	P> t	[95% Conf. Interval]	
gender	.4239033	.1064038	3.98	0.000	.2146106	.633196
age	-.0217692	.0022703	-9.59	0.000	-.0262349	-.0173035
weight	.0051612	.0029872	1.73	0.085	-.0007145	.0110369
height	.0331205	.0055303	5.99	0.000	.0222426	.0439984
a_b	-.6506783	.131462	-4.95	0.000	-.9092597	-.392097
_cons	-1.81837	.8124922	-2.24	0.026	-3.416514	-.2202252

Results (2)

mean PEFr

- 466.1 L/min \pm 164.5 sd from spirometer
- 426.3 L/min \pm 151.6 sd from PIKO-1

PIKO-1 under-estimated PEFr values by 8 % (p < 0.001) systematically.



Regressione pefr_sp contro gender, age, height, weight e a_b

Regression with robust standard errors

Number of obs = 346
F(5, 340) = 113.80
Prob > F = 0.0000
R-squared = 0.5662
Root MSE = 99.229

pefr_pk	Coef.	Robust Std. Err.	t	P> t	[95% Conf. Interval]	
gender	99.39961	17.22485	5.77	0.000	65.51892	133.2803
age	-2.071398	.3679118	-5.63	0.000	-2.795068	-1.347728
weight	1.968532	.5191659	3.79	0.000	.9473501	2.989713
height	1.724437	.8998015	1.92	0.056	-.0454419	3.494315
a_b	-110.9246	22.41911	-4.95	0.000	-155.0222	-66.82699
_cons	59.37411	135.4474	0.44	0.661	-207.0462	325.7945

Regressione fevl_sk contro gender, age, height, weight e a_b

Regression with robust standard errors

Number of obs = 346
F(5, 340) = 133.38
Prob > F = 0.0000
R-squared = 0.6232
Root MSE = 101.01

pefr_sp	Coef.	Robust Std. Err.	t	P> t	[95% Conf. Interval]	
gender	106.4889	16.46356	6.47	0.000	74.10563	138.8722
age	-2.330821	.3688085	-6.32	0.000	-3.056255	-1.605388
weight	2.860995	.5355979	5.34	0.000	1.807493	3.914498
height	1.976012	.8765409	2.25	0.025	.2518861	3.700138
a_b	-115.3827	23.48612	-4.91	0.000	-161.5791	-69.18629
_cons	-2.97733	128.3911	-0.02	0.982	-255.5183	249.5636

Conclusions

- 1) The precision of both PIKO-1 measures proves good, even though slightly lower than claimed;
- 2) PEF_R and FEV₁ measures should be reset by two different constants, being BTPS conversion considered;
- 3) PIKO-1 proves a suitable and reliable device for both the FEV₁ and PEF_R personal monitoring in obstructive patients.