PIKO-1, A NOVEL OPPORTUNITY FOR THE PATIENT'S PERSONAL PEFR AND FEV_1 ELECTRONIC MONITORING: A COMPARISON STUDY VS A CONVENTIONAL SPIROMETER

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

° Dal Negro RW, * Turco P, ° Turati C, ° Bisato R,
^ Guerriero M, # Sandri M.

° Lung Dept, Bussolengo General Hospital, Verona,
** National Union for Asthma Patients;*
^ ESI Dept, Statistical Section, and # CIDE Dept.,
University of Verona - Italy

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 PEFR, the maximum flow rate that can be generated during a forced expiratory manoeuvre.

Introduction (2)

Altought FEV_1 is the single best measure for assessing severity of airflow obstruction, PEFR 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 PEFR 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 FEV_1 personal check;
- PEFR range = 15 - 999 L/min (resolution 1L/min);
- FEV_1 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 PEFR and FEV_1 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 ± 19.0 sd;
- mean weight = 72.6 kg ± 15.0 sd;
- mean height = 168.1 cm ± 11.9 sd

- Each subject performed 3 sequential measures from PIKO-1 and from a conventional spirometer (Masterscreen, Jäger, Germany).

Statistics

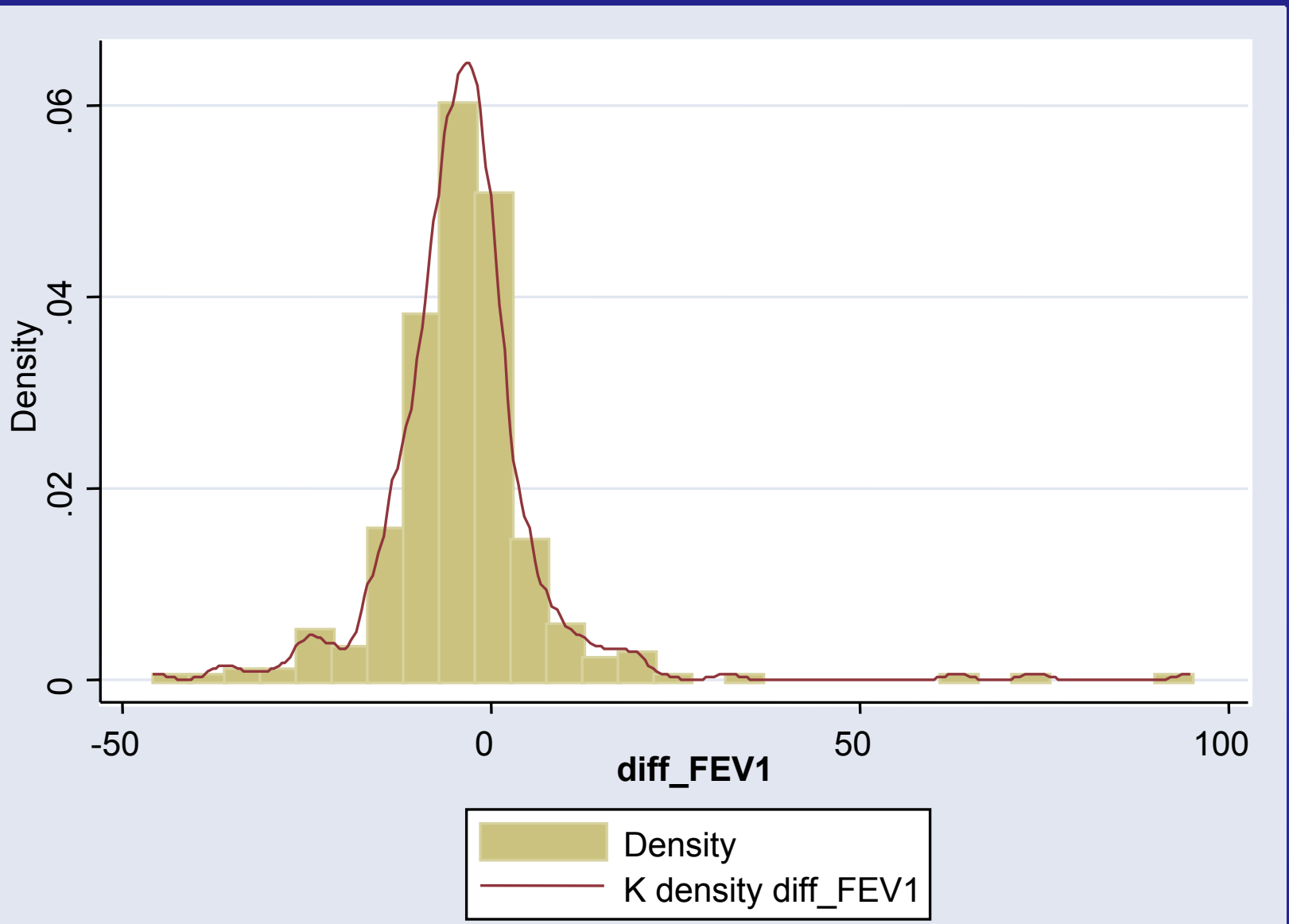
- Wilcoxon signed-rank test;
- Sign test;
- $p<0.05$ accepted

Results 1:

mean FEV_1

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

PIKO-1 over-estimated FEV_1 values by 4 % ($p < 0.001$) systematically


Density
0
.02
.04
.06
-50
0
50
100
diff_FEV1
Density
K density diff_FEV1

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

------------------------------------------------------------------------------
             |               Robust
      fev1_sp |      Coef.   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

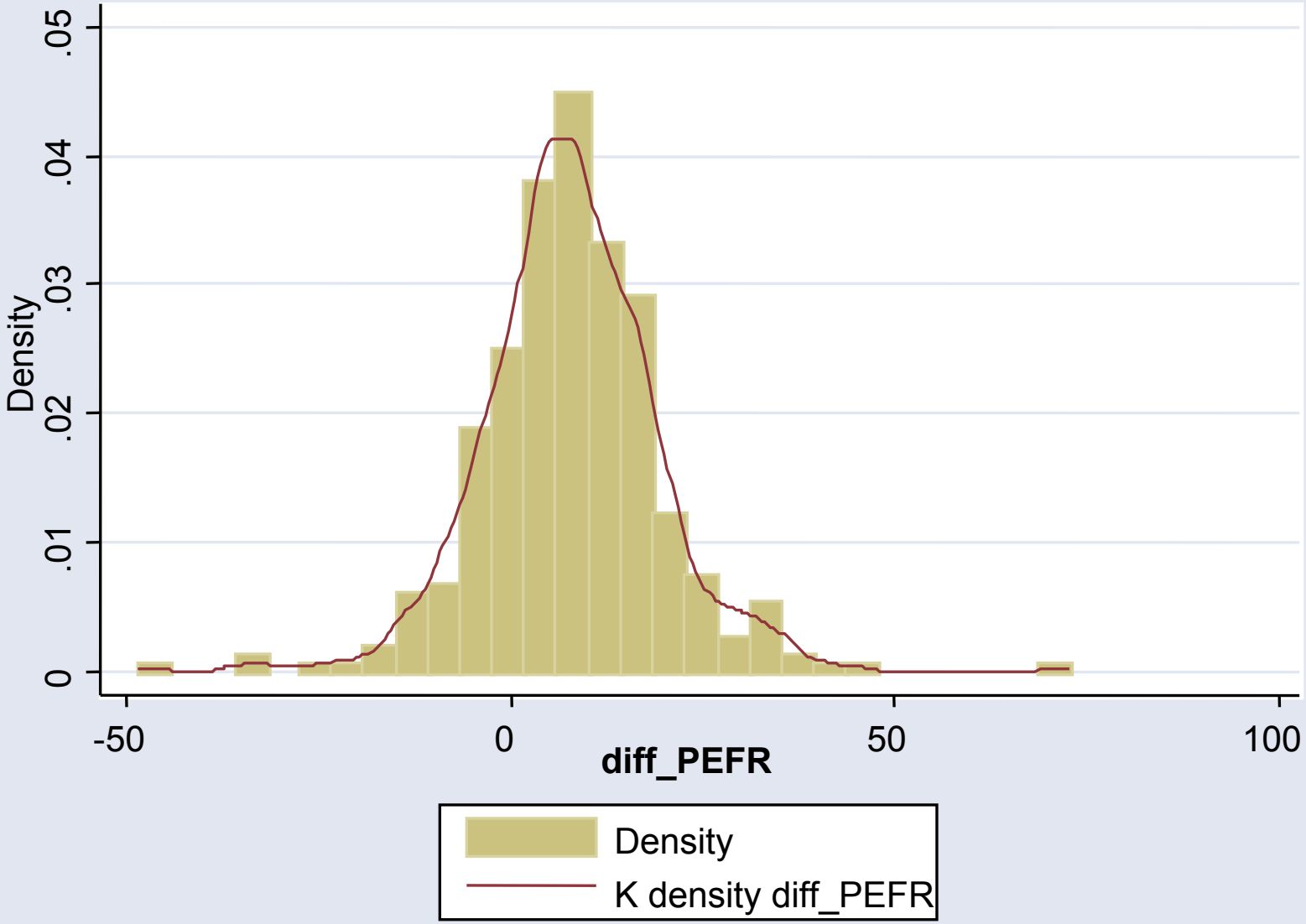
```
Regression with robust standard errors                Number of obs =     346
                                                      F(  5,   340) =  147.12
                                                      Prob > F      =  0.0000
                                                      R-squared     =  0.6663
                                                      Root MSE      =  .64637

------------------------------------------------------------------------------
             |               Robust
      fev1_pk |      Coef.   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 ± 164.5 sd from spirometer
- 426.3 L/min ± 151.6 sd from PIKO-1

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


Density
0
.01
.02
.03
.04
.05
-50
0
50
100
diff_PEFR
Density
K density diff_PEFR

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 fev1_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) PEFR and FEV_1 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 PEFR personal monitoring in obstructive patients.