

Evaluation of a novel smart e-device to monitor domiciliary peak nasal inspiratory flow (PNIF) and peak expiratory flow (PEF) in patients with severe asthma and nasal polyps taking dupilumab



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Background

- Mobile phone-based applications are accessible and convenient for:
 - monitoring symptoms
 - response to treatment

Smart Peak Flow Device

- Smart Respiratory Products Ltd
- palm-sized turbine
- measures PNIF (peak nasal inspiratory flow – airflow through the nose)
- measures PEF (peak expiratory flow – airflow in asthma)
- bluetooth or 3.5mm headphone jack connection
- cloud-based e-diary app
- iOS or android





Objective

- To ascertain whether this was an **effective** method for domiciliary monitoring of nasal and asthma symptoms and whether this could **detect clinically relevant improvements** in control in patients with severe asthma and CRSwNP treated with dupilumab

Method

- Prospective evaluation
- 13 patients (out of 21 on trial)
- Uncontrolled type 2 high severe asthma and CRSwNP
- Dupilumab 300mg q2wk for 12 weeks
- Patients recorded daily asthma and nasal e-diaries
- Analogue PNIF and spirometry PEF were recorded at baseline and week 12 for comparison
- EudraCT 2021-005593-25

Asthma	CRSwNP
PEF	PNIF
MART inhaler use (puffs/day)	Hyposmia VAS 0-10
Asthma symptoms VAS 0-10	Nasal congestion VAS 0-10

Table showing information recorded on electronic device

Results

- Mean age: 53 years
- Female: 7/ Male: 6
- Mean nasal polyp score: 4.23
- SNOT 22 score: 59
- ACQ score: 2.79 (poor asthma control >1.5)
- FEV1: 78%

Weekly mean e-diary results

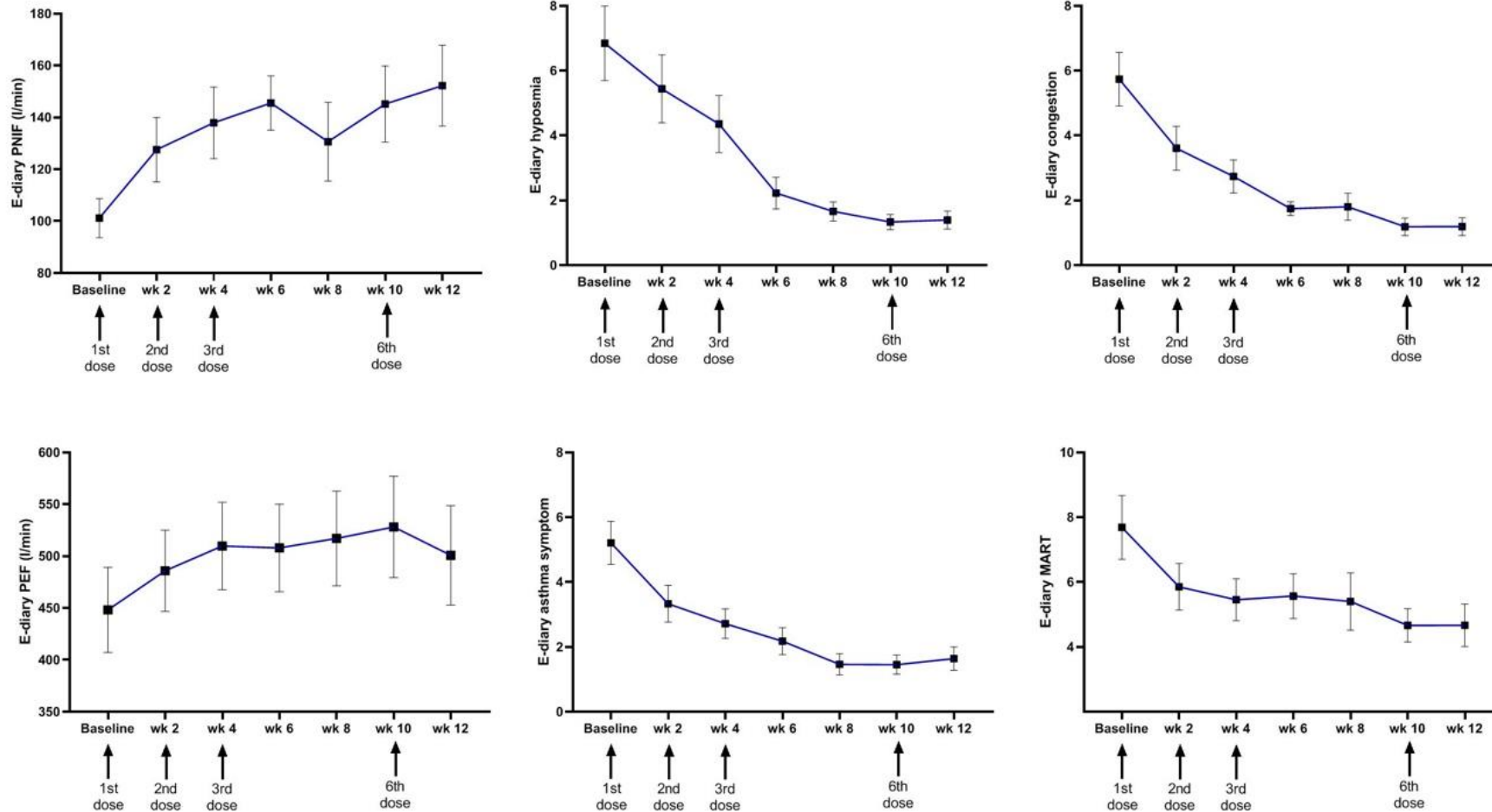


Figure: e-diary recordings for PNIF and PEF, VAS symptoms (out of 10), and MART inhaler use (puffs per day) at baseline and during 12 weeks of dupilumab. Values are means and SEM

Serial daily e-diary profiles

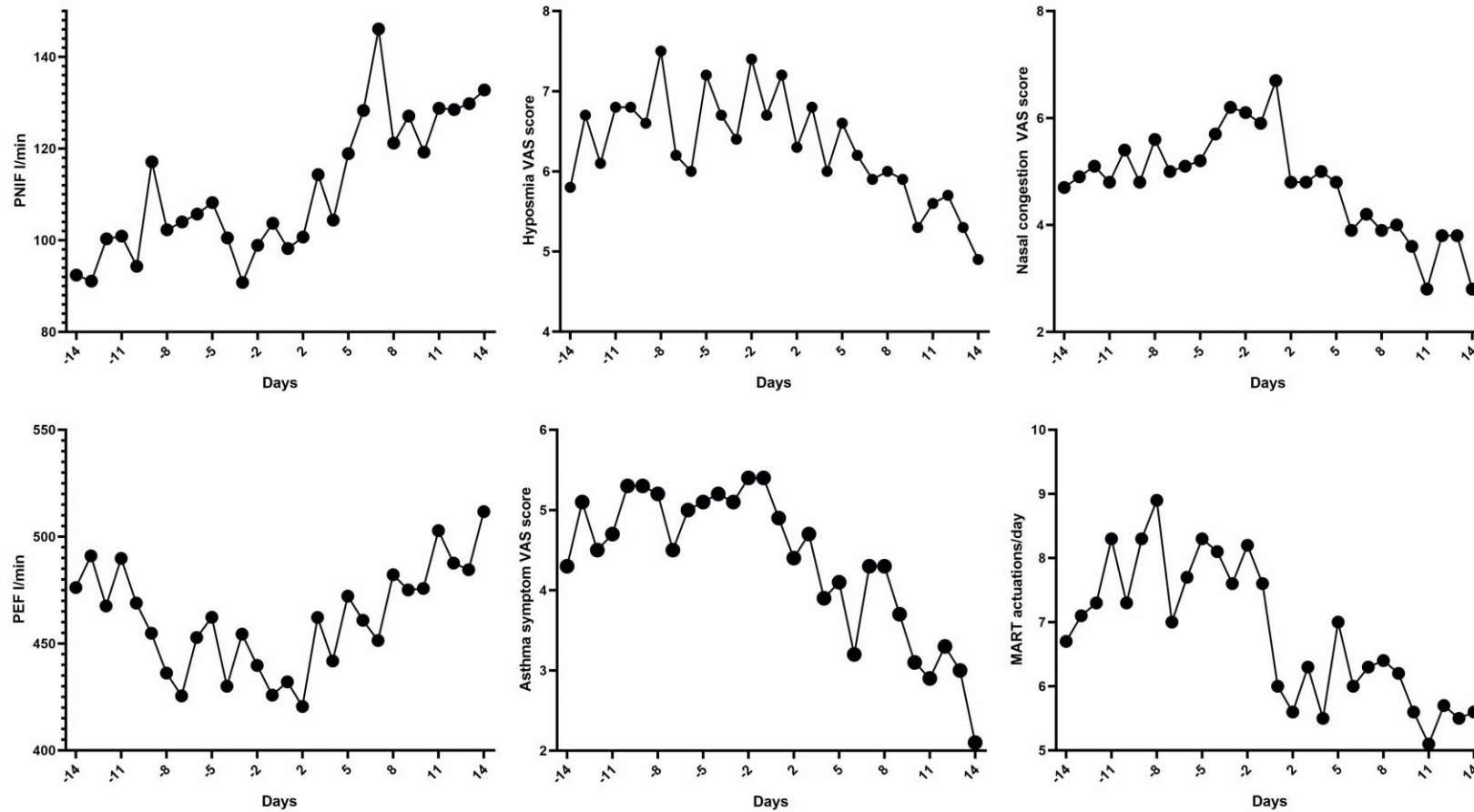
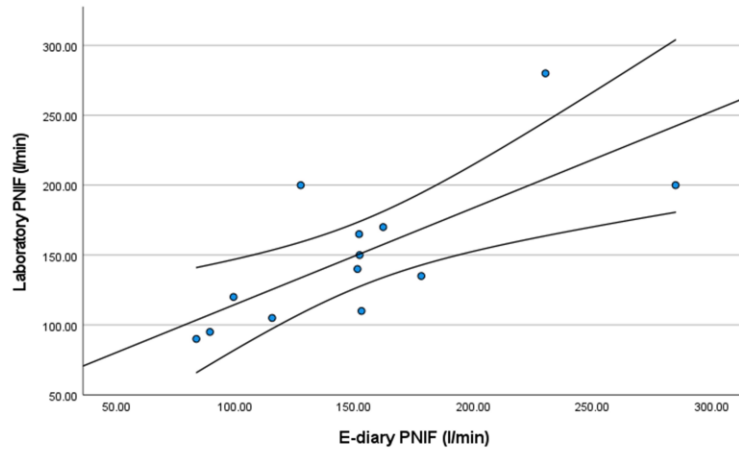
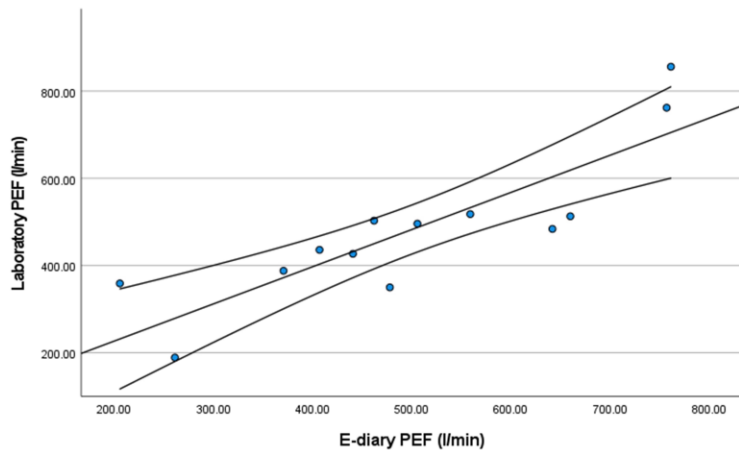


Figure: Serial daily e-diary profiles for the last 2 weeks of the run-in period (as days -1 to -14) and the subsequent first 2 weeks of the dupilumab treatment period (as days 1-14). Mean daily values are depicted for visual analogue scale scores (out of 10)

Regression/Difference



$R^2 = 0.53$
($p < 0.005$)



$R^2 = 0.74$
($p < 0.001$)

Figure 1: Regression analysis with 95%CI for e-diary and laboratory readings for PNIF and PEF at 12 weeks

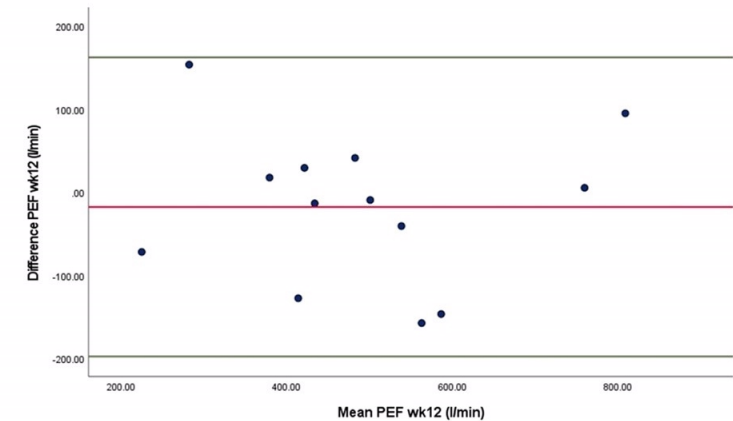
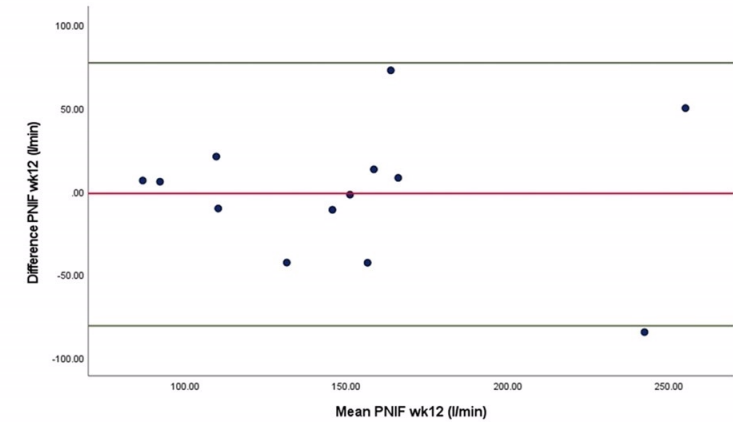


Figure 2: Bland Altman plots for agreement between e-diary and visit recordings of PNIF and PEF after 12 weeks of dupilumab

Conclusion

- The smart e-device and e-diary was suitable for detecting clinically relevant improvements in objective and subjective outcomes in response to dupilumab in the upper and lower airway
- There was good agreement with the lab-based 'gold standard' devices for PNIF and PEF

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- The University of Dundee acted as sponsor for the study.
- The smart e-devices were a gift from Smart Respiratory Products while University of Dundee provided unrestricted partial financial support to Smart Respiratory Products towards software development of the beta-app to measure PNIF and adding the VAS for hyposmia and congestion scores



Any
questions?

Table of weekly results

	Wk 2	Wk 4	Wk 6	Wk 8	Wk 10	Wk 12
PNIF	26 (11)*	37 (14)	44 (10)	29 (14)	44 (13)	51 (14)**
Hyposmia	1.41 (0.60)*	2.49 (0.86)	4.62 (1.09)	5.19 (1.22)	5.52 (1.15)***	5.45 (1.14)
Congestion	2.13 (0.33)***	3.00 (0.65)	4.00 (0.85)	3.94 (1.02)	4.55 (0.92)***	4.55 (0.85)
PEF	38 (13)*	62 (13)	60 (16)	69 (16)	80 (21)**	53 (19)
Asthma	1.88 (0.39)***	2.49 (0.54)	3.03 (0.69)	3.75 (0.75)	3.75 (0.81)***	3.57 (0.67)
MART	1.83 (0.60)*	2.23 (0.79)	2.12 (0.89)	2.29 (0.94)	3.02 (0.89)**	3.02 (1.02)

Values are means (SEM) *p<0.05, **p<0.01, ***p<0.001 for pairwise comparison at 2 weeks and at peak vs baseline. Peak nasal inspiratory flow (PNIF), peak expiratory flow (PEF), visual analogue scale symptom scores (out of 10) for hyposmia, congestion, global asthma symptoms (asthma), maintenance and reliever therapy (MART) use with beclomethasone/formoterol (actuations/day)