

11.01 Use of digital measurement of medication adherence and lung function to guide the management of uncontrolled asthma: The INCA Sun randomized clinical trial

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Objective: Treatment decisions guided by digitally-acquired data on adherence, inhaler technique and peak flow were compared with current methods. **Design:** Patients >18 years with severe uncontrolled asthma were enrolled to a 32-week multicentre single-blind randomized clinical trial (INCA Sun) comprising a 1-week run-in period, 3 education visits over 8-weeks, and 3 treatment adjustment visits over 24-weeks in ten asthma clinics.

Intervention: The active group had personalized biofeedback on inhaler adherence, technique, and PEF. Treatment decisions were informed by digital data. The control group had adherence coaching, inhaler training, and an action plan. Treatment was adjusted based on pharmacy refill rates, asthma control, and risk of exacerbations. Both groups used a digitally-enabled inhaler and digital PEF. **Results:** Of the 220 patients who consented to participate, 213 were randomized (control: 105; active: 108) and 200 completed the 32-week study. The mean age was 47[SD, 14.9] years, 137[64%] women participated. At week 32, 11(11%) active and 21(21%) control patients required add-on biologic therapy OR 0.42, 95%CI [0.189-0.95], p=0.038). Three of 19(16%) active and 11 of 25(44%) control patients who started on FP 500mcg/day were increased to 1,000mcg/day (OR 0.26; 95%CI [0.07–0.99], p=0.049). Twenty-six of 83(31%) active and 13 of 73(18%) control patients who started on FP 1000mcg/day were reduced to FP 500mcg/day, OR 2.11, 95%CI [1.01–4.74], p=0.047). Despite a lower treatment burden were no differences in asthma control, lung function, T2 inflammation, nor exacerbations between the two groups. No safety differences were observed.

Conclusions and relevance: Evidence-based care informed by digital data safely led to a significantly lower treatment burden.

Conflict of Interest: *None to declare*