Adherence and Asthma Control in Patients Using FF/VI With and Without an Inhaler Sensor

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Aims

- Asthma is a major cause of morbidity in the U.S. and imposes a substantial burden on patients and payers. As such, understanding patients' adherence to prescribed therapies is essential to determining whether they are receiving the full clinical benefit of these medications.
- New advances in technology, such as remote inhaler sensors, are providing much needed insight into patients' actual use of prescribed therapies in real-time, using data collection tools that are unobtrusive, accurate, and have minimal patient burden.
- The objective of this study was to examine descriptively the effect of sensor technology on adherence, albuterol use, and asthma control among adult patients on once daily Ellipta inhaler-based fluticasone furoate/vilanterol (FF/VI).

Methods

- A prospective administrative claims-linked, 6-month observational study
- Patients who met the following criteria were identified in the Optum Research Database in July 2017 using medical and pharmacy claims data from June 1, 2016 to May 31, 2017:
  - ≥18 years of age
  - ≥1 FF/VI and albuterol metered dose inhaler (MDI) dispensing in the prior 6 months of the identification period
  - Continuous and current enrollment in Optum affiliated health plans during the 12-month identification period
  - Had no COPD-related diagnosis code during the identification period
- Subjects were asked to complete a baseline mailed survey, followed by web surveys at 3 and 6-month follow-up to collect patient reported measures, including the Asthma Control Test (ACT)
- Subjects were asked to utilize Propeller Health sensors with their albuterol MDI and FF/VI Ellipta devices for the 6-month follow-up period, to capture the date, time, and number of FF/VI and albuterol MDI actuations in real-time
- Subjects' pharmacy claims data for the 6-month follow-up were examined to assess inhaler treatment patterns, including mean number of dispensings, proportion of days covered (PDC), and the percent with asthma medication ratio (AMR) ≥0.50

$$\text{PDC} = \frac{\text{Total days covered by index medication in follow-up period}}{\text{Total days in follow-up}}$$

$$\text{AMR} = \frac{\text{Number of dispensings for index controller medication}}{\text{Sum (dispensings for index controller + dispensings for albuterol MDI)}}$$

- Study Arms:
  - Sensor Arm: Subjects who received and used the mailed Propeller Health sensors and data hub for albuterol MDI and FF/VI Ellipta devices over the 6-month period and were asked to complete the surveys at baseline, 3 months, and 6 months
  - No-Sensor Arm: Subjects who opted-out of sensor use but were asked to complete the surveys at baseline, 3 months, and 6 months
- Statistics: All variables were assessed descriptively and were compared between patients in the Sensor Arm and No-Sensor Arm using t-tests for continuous variables and chi-squared tests for categorical variables.

Results

- 127 subjects enrolled in the Sensor arm and 61 enrolled in the No-Sensor arm. Baseline characteristics were similar between the Sensor and No-Sensor arms: mean age 47.1 vs. 48.0 years, percent female 64.6% vs. 70.5%, baseline mean ACT scores (SD) 19.1 (3.90) vs. 19.6 (4.26), and ACT ≥ 20 was 54.3% vs. 63.9%, respectively **(Table 1).**

Table 1. Demographic Comparison
June 1, 2016 – May 31, 2017

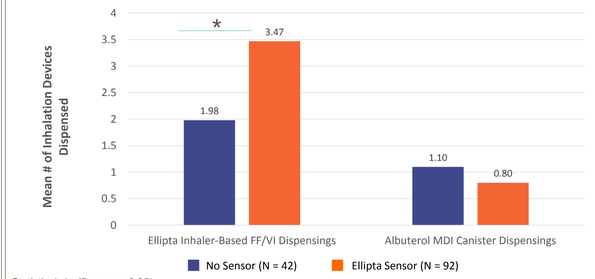
	No Sensor (N=61)	Sensor (N=127)	P-value
Age – Mean (SD) Years	47.98 (13.49)	47.13 (12.09)	0.662
Female – %	70.49	64.57	0.420
Race – %, Asian	6.56	0.79	0.021*
Black or African American	8.20	4.72	0.342
Native Hawaiian/other Pacific Islander	4.92	0.79	0.066
White	86.89	91.34	0.343
Other Race	4.92	3.15	0.549
BMI – Mean (SD)	29.87 (7.60)	31.12 (8.39)	0.325
Baseline ACT Scores – Mean (SD)	19.62 (4.26)	19.06 (3.90)	0.372
ACT ≥20 – %	63.93	54.33	0.212

Statistical significance p≤0.05*

Claims-Identified Treatment Patterns during a 6-Month Follow-Up Period:

- Mean FF/VI Ellipta pharmacy dispensings were significantly higher in the Ellipta Sensor arm vs. the No Sensor arm. In comparison, mean Albuterol MDI canister dispensings were higher in the No Sensor arm vs. the Ellipta Sensor arm; this difference was not statistically significant. (**Figure 1**).

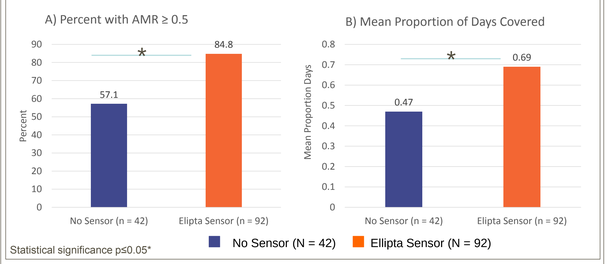
Figure 1. Pharmacy claim dispensings over 6-month follow-up period



Statistical significance p≤0.05*

- Significantly more subjects in the Ellipta Sensor arm had an AMR ≥ 0.5. **(Figure 2)** The mean PDC was also significantly higher in the Ellipta Sensor arm than the No Sensor arm. (**Figure 2).**

Figure 2. Pharmacy claims AMR and PDC data over 6-month follow-up period

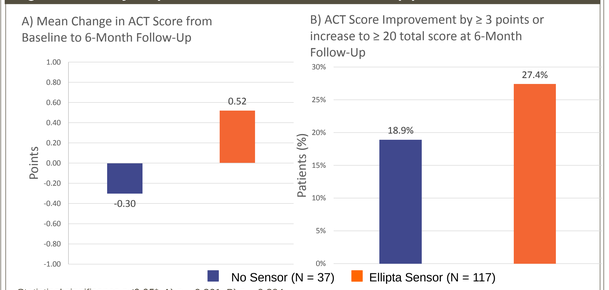


Statistical significance p≤0.05*

Survey-Based Outcomes during a 6-Month Follow-Up Period:

- Mean ACT score change from baseline and percent of patients with improvement in ACT scores of ≥ 3 points or change in ACT to ≥ 20 points overall were not statistically different between the two groups but higher in the Sensor arm (**Figure 3)**

Figure 3. Survey response data over 6-month follow-up period

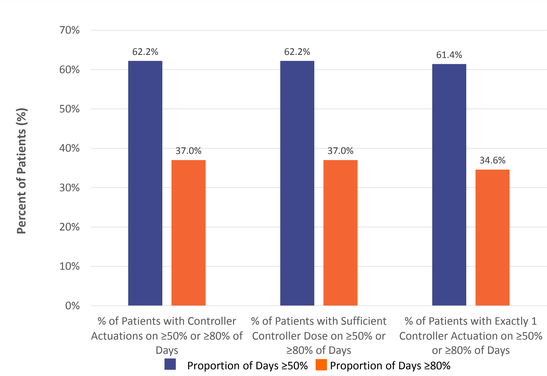


Statistical significance p≤0.05*. A) p = 0.361; B) p = 0.304

Sensor-derived Outcomes during a 6-Month Follow-Up Period:

- Sensor-derived inhaled controller dose count adherence was descriptively compared with the claims-based measures of the PDC for the inhaled FF/VI controller medication among patients in the Ellipta Sensor arm, for the 6-month follow-up period.
- Sensor-derived mean controller use adherence was significantly less than claims-derived PDC (0.61 and 0.69 respectively, p = 0.001). Similarly, Sensor-derived mean controller dose count adherence was significantly less than claims-derived PDC (0.58 and 0.69, p < 0.001).
- As shown in **Figure 4**, approximately 60% of Ellipta Sensor patients actuated their controller medication and received a sufficient controller dose for at least 50% of the follow-up period. Over 30% of patients were adherent to their controller medication for at least 80% of the follow-up period.

Figure 4. FF/VI Ellipta Sensor data over 6-month follow-up period (N = 127)



Conclusions

- This exploratory study shows that patients using a sensor that monitors their medication-taking behavior may be more likely to use their controller therapy, which could thereby improve asthma control and reduce albuterol use.
- Limitations of this study are rooted in the survey design, as all surveys may be subject to sampling error, coverage error, and measurement error. Participants in this study were selected from among those with commercial coverage in a national health plan, which may not be representative of a sample of all asthma patients.

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