

BACKGROUND

Chronic rhinosinusitis (CRS) is a high-prevalence condition (~15% in the United States) producing significant morbidity which is characterized by chronic mucosal inflammation of the nose and paranasal sinuses.^{1,2}

Though usually effective for allergic rhinitis, conventional nasal steroid sprays frequently produce unsatisfactory efficacy in the treatment of CRS. This is due to their inability to deliver steroid high/deep in the nasal cavity (above the inferior turbinate, behind the uncinate process) to key anatomical regions (eg, the ostiomeatal complex or OMC) where sinus ostia ventilate and drain.³

Oral steroids are often effective for CRS, but have many side effects and symptoms recur after discontinuation. Unfortunately, most CRS patients are frustrated with the symptom relief achieved with conventional intranasal steroids (INS), ranging from 63-88% among groups of patients with moderate to severe symptoms and without or with complicating polyps (CRSsNP / CRSwNP).²

EDS-FLU (Exhalation Delivery System with Fluticasone, **Xhance™**) uses a new approach to intranasal drug delivery system to achieve high/deep deposition. It has been extensively studied in CRSwNP and CRSsNP, and shown to reduce all four defining symptoms of CRS (congestion, rhinorrhea, facial pain/pressure, hyposmia), need for endoscopic sinus surgery, polyp size, and to improve general and disease-specific health-related quality of life.

EDS-FLU, therefore, has potential to improve patient satisfaction with disease treatment. Patient satisfaction with disease treatment is a measure that has been shown to correlate with a wide variety of improved outcomes, including quality of care metrics, reduced readmissions, and reduced inpatient mortality.⁴

Improvement of healthcare quality is of interest to all parties involved in health care decision-making (patients, physicians, payers, policymakers). This creates an opportunity to identify areas of suboptimal outcomes and target them for patient education, healthcare delivery optimization, implementation of new technologies, or a combination of the above. Increasingly, patient satisfaction is being used as a metric in payment systems for quality.⁵

This analysis reports the impact of EDS-FLU on patient-reported treatment satisfaction and analyzes effect on treatment satisfaction from a population perspective.

METHODS

An Excel-based simulation was designed to estimate the percentage of patients with CRSwNP and CRSsNP treated with a conventional INS vs EDS-FLU who achieve treatment satisfaction.

The simulation was conducted from the perspective of the general U.S. population.

Study Population

Subjects with CRSwNP and CRSsNP using EDS-FLU in 2 open-label clinical trials (EXHANCE-3 and EXHANCE-12) were surveyed. All subjects were from the United States.

Data Sources

Treatment Satisfaction

Patients were asked to complete a survey about their experience with EDS-FLU during or following their participation in the clinical trials.

Patients were asked to assess their overall level of satisfaction with EDS-FLU and with the conventional INS used prior to EDS-FLU.

For example, satisfaction was assessed by asking patients: "Overall, how satisfied were/are you with the product that you are using as part of the clinical trial? Please use a 0-10 scale, where 0 means "not at all satisfied" and 10 means "extremely satisfied."

Patients were classified as "satisfied" if they scored >5.

CRS Prevalence

CRS prevalence in the general U.S. adult population was obtained from a nationally-representative survey of U.S. adults.²

Population Satisfaction

Treatment satisfaction per 1 million adults in the U.S. for both conventional INS and EDS-FLU was calculated based on treatment satisfaction rates for INS and EDS-FLU in treatment of CRS and on CRS prevalence.

Analytical Methods

Inputs above and listed in **Table 1** were used to estimate the potential population-level impact of treating with EDS-FLU vs currently available conventional INS (such as **Flonase™** or **Nasonex™**) on treatment satisfaction.

Table 1. Treatment Satisfaction Model Inputs

Population	1,000,000
Prevalence of CRS	11.5%
Patients with CRS treated with INS in the last year	88%
% satisfied with current standard of care (INS)	28%
% satisfied with EDS-FLU	88%

The number needed to treat (NNT) was calculated using the formula, 100/absolute risk reduction, (i.e. the difference in treatment satisfaction rate between INS and EDS-FLU).

A sensitivity analysis was conducted to assess the impact of variation in the prevalence of CRS, and of different rates of adopting treatment with EDS-FLU.

RESULTS

Survey Respondents

From a total of 930 CRSwNP and CRSsNP patients in EXHANCE-12 and EXHANCE-3, 83 completed the satisfaction survey (8.9%), including 6 patients (7% of respondents) who stopped using EDS-FLU and did not finish the trial.

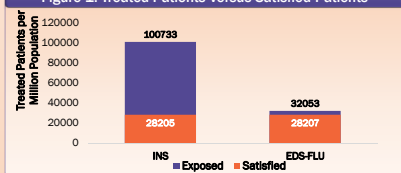
Treatment Satisfaction Rating

Consistent with prior data, a low proportion of respondents reported satisfaction with conventional INS (28% satisfied). A high proportion of respondents reported satisfaction (88% satisfied) after treatment with EDS-FLU.

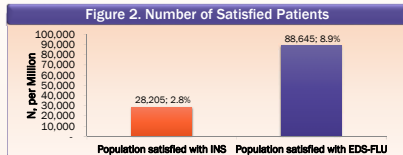
Impact on Population Satisfaction

Similar numbers of treatment-satisfied patients (28,200 patients; 2.82% per 1M people in the general population) could be achieved by treating many fewer patients with EDS-FLU than are currently being treated with conventional INS (32,053 patients treated with EDS-FLU achieves the same number of treatment-satisfied patients as treating 100,733 patients with current INS (**Figure 1**)).

Figure 1. Treated Patients Versus Satisfied Patients



Alternatively, population level treatment satisfaction is greatly increased by increasing the % of CRS patients treated with EDS-FLU rather than current INS. At the extreme, if 100% of CRS patients were treated with EDS-FLU rather than current INS, there is potential to increase the number of satisfied patients to 88,645, an absolute increase of 6.1% at the population level. (**Figure 2**)



The NNT to increase patient satisfaction at the CRS patient level was 1.67.

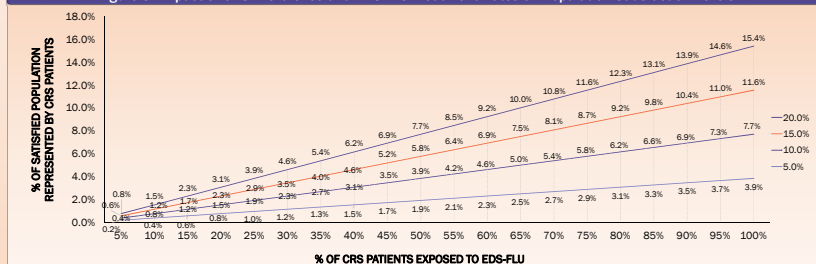
Sensitivity Analysis (Figure 3)

Every 5% increase in exposure to EDS-FLU among CRS patients (approximately 537 patients), produces a 0.45% increase in patient satisfaction at the population level at the current prevalence for CRS.

Every 5% increase in CRS prevalence produced 0.2% increase in satisfaction at the population level.

A 5% increase in both prevalence and treatment exposure was associated with a 0.75% increase in treatment satisfaction at the population level.

Figure 3. Impact of CRS Prevalence and EDS-FLU Treatment Rates on Population Satisfaction Levels



References

- Orlandi RR, Kingdom TT, Hwang PH, et al. *Int Forum Allergy Rhinol*. 2016;6 suppl 1:522-5209.
- Palmer J, Messina J, Bleich R, Cozart K, Mahmoud R. Health Care for Chronic Rhinosinusitis (CRS) Symptoms-A Cross-Sectional, Population-Based Survey of US Adults Meeting Symptom Criteria for CRS. Poster session presented at: Annual Meeting of the American Academy of Allergy Asthma & Immunology; March 3-6, 2017; Atlanta, GA.
- Djupesland PG. Nasal drug delivery devices: characteristics and performance in a clinical perspective - a review. *Drug Deliv and Transl Res*. 2013;3:42-62.
- Measuring patient satisfaction: A bridge between patient and physician perceptions of care. *Health Affairs Blog* Web site. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3014705/> [Measuring patient satisfaction: a bridge between patient and physician perceptions of care]. Published May 9, 2014. Accessed September 24, 2017.
- Berkowitz, B. The patient experience and patient satisfaction: Measurement of a complex dynamic. *Online J Issues Nurs*. 2006;21(1):1.

LIMITATIONS AND DISCUSSION

The analyzed population (drawn from the EXHANCE trials) included patients with moderate to severe disease, and may therefore be more representative of patients treated by specialists such as Allergists or ENTs.

Treatment satisfaction among various sub-populations in a real world setting may differ (eg, due to symptom severity, tolerability or availability of the product) and the measured satisfaction rates may have been subject to recall or respondent bias, any of which may effect satisfaction point estimates. However, the size of the effect is so substantial that even large variations in satisfaction rates do not change the overall conclusion.

Population-level treatment satisfaction may also vary with care for comorbid conditions; however, given the high degree of morbidity associated with CRS, it is likely that addressing the symptoms of CRS has a large direct influence on overall satisfaction with care.

CONCLUSIONS

In this population model, treatment of chronic rhinosinusitis with EDS-FLU rather than current nasal steroids has potential to greatly increase population-level patient treatment satisfaction, and thus quality of care, with a low number-needed-to-treat.

Treatment satisfaction at the population level was more responsive to increasing the rate of patient exposure to EDS-FLU than to change in disease prevalence.