

BACKGROUND

- CRS with and without nasal polyps (CRSwNP and CRSsNP) is a common chronic inflammatory condition characterized by a constellation of symptoms including nasal congestion/obstruction, rhinorrhea, facial pain/pressure, and reduction/loss of smell.¹
- Other important symptoms of CRS such as fatigue and bodily pain, sleep dysfunction, and depression are underappreciated despite their frequent presence.¹
- The burden of disease attributable to CRS with and without nasal polyps is substantial at the individual and societal level. CRS impairs quality of life (QoL) to a similar degree as CHF, COPD, and Parkinson's disease, and the overall annual economic burden of CRS in the United States (U.S.) was estimated at \$22 billion (direct and indirect costs) in 2014.^{2,3}
- The estimated prevalence of CRS is high, but specific estimates vary (range:15-40 million) and are often derived from administrative healthcare databases rather than primary population sources.
- This population-based survey was conducted to better characterize the prevalence, burden of illness, and characteristics of the U.S. adult population with symptoms of CRS, including CRSwNP and CRSsNP.

METHODS

- Population survey of 10,336 U.S. adults randomly drawn from a representative general panel of 4.3 million.
- The survey captured data across a broad range of related symptoms and also captured patient-reported severity and duration.
- Participants reporting sufficiently severe and chronic symptoms were categorized into CRS subgroups based on self-reported symptoms and severity (at least 2 of the core CRS symptoms lasting more than 8 consecutive weeks, with congestion or rhinorrhea being one of the symptoms).

Patient-Reported Data Collected

- General health symptoms
- CRS-defining symptoms in past 12 months
- Physician-diagnosed conditions
- Duration of nasal symptoms and medication use in past 12 months to treat nasal symptoms
- Presence or absence of nasal polyps

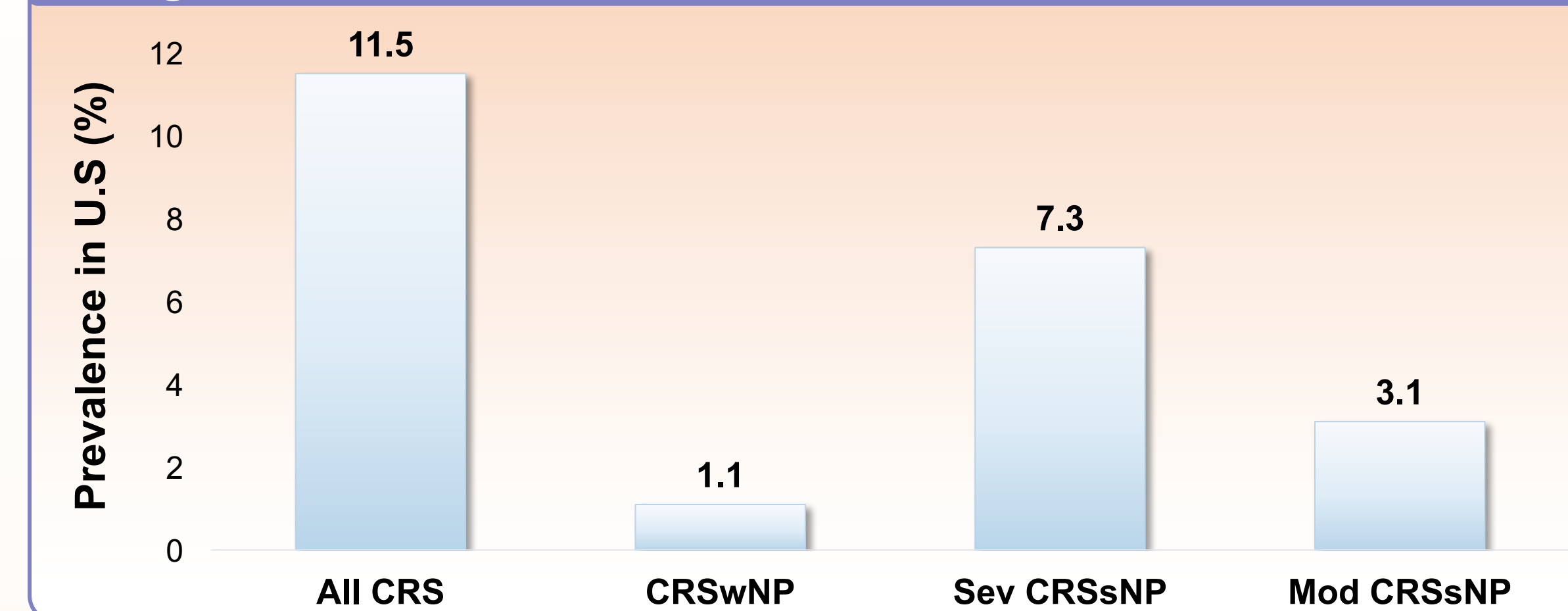
Criteria to Assess Disease Severity

- Severity of the diagnosed condition in past 12 months
- Severity of symptoms on a typical day in past 12 months
- 'Bother' (burden) of symptoms
- Use of intranasal steroids for >60 days in past 12 months
- Number of flares in past 12 months
- Use of oral steroids for symptom control in past 12 months

RESULTS

- Survey respondents were found to be closely representative of the U.S. adult population in terms of geographic distribution (including USDA climate zones), socio-economic status, education, and comorbid illnesses when compared to known distributions (e.g., U.S. Census).
- Approximately 11.5% of respondents self-reported symptoms meeting diagnostic symptom criteria for CRS and were defined as CRS patients for the purpose of this analysis. (Figure 1)

Fig 1. Prevalence of CRSwNP and Moderate-Severe CRSsNP



- A substantial number of CRS patients reported prior medical or surgical interventions for their CRS symptoms. (Table 1)

Table 1. Patient-Reported Medication and Surgical History

Characteristic	CRSwNP	Severe CRSsNP	Moderate CRSsNP
Surgery for nose, sinus in past 12 months (%)	8%	2%	0.3%
Surgery for nose, sinus – ever (%)	52.2%	14.7%	12.8%
Treated with intranasal steroids for nose, sinus in past 12 months (%)	92.5%	86.3%	88.9%
Oral steroids used for nose, sinus in past 12 months (%)	71.2%	36.3%	31.4%

- 10.4% reported having nasal polyps, half of which reported prior nasal surgery while 14.7% that did not report having polyps had prior nasal surgery.
- Frequencies of each core CRS symptom were similar in patients with and without polyps except that patients with polyps and those with severe CRSsNP reported notably higher rates of facial pain/pressure (60-65%) and loss of smell/taste (46-56%). Nasal congestion/obstruction (94-97%) and drainage (89-92%) were the most frequently reported core symptoms.
- CRS symptoms adversely impact multiple areas of daily life, as reported by patients, despite available treatment options. Adverse effects were greatest on sleep and mood, and notable on work/school, social activities, exercise, and recreation. (Figure 2)

Fig 2. Impact of Symptoms on Daily Activities

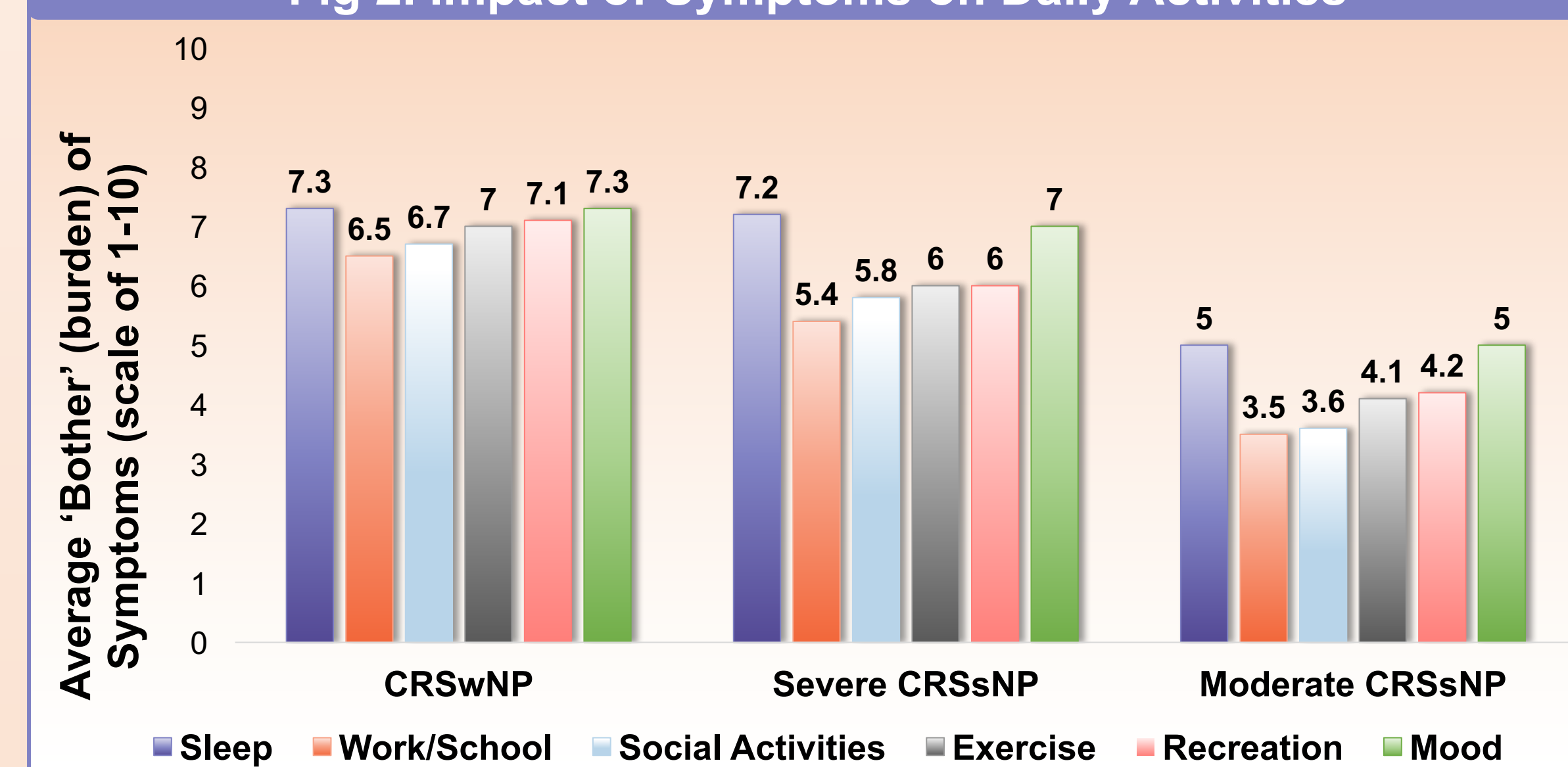


Figure 2. Patients were asked: In the past 12 months, when you had these symptoms, on a typical day, how much did these affect you in the following areas? Please use a 0-10 scale, where 0 means "not at all" and 10 means "completely."

- Symptoms are Often Severe:** On a 0-10 scale, with 10 being "extremely bothersome", patients with CRSwNP rated their symptom severity a mean of 8.2; severe CRSsNP patients rated a mean of 9.4.
- Healthcare Use is High:** ~60% of CRSwNP and severe CRSsNP self-reported ≥5 doctor visits in the previous year for nasal and sinus symptoms. They also self-report more ER visits or overnight hospitalizations than moderate CRSsNP patients.
- Current Nasal Steroid Sprays are Suboptimal:** A large majority (~90%) of patients with CRSwNP and severe CRSsNP using intranasal corticosteroids (INCS) report being frustrated with the inadequate symptom relief produced by their current INCS spray. (Figure 3)

Fig 3. Patients Frustrated with Symptom Relief of Current INCS

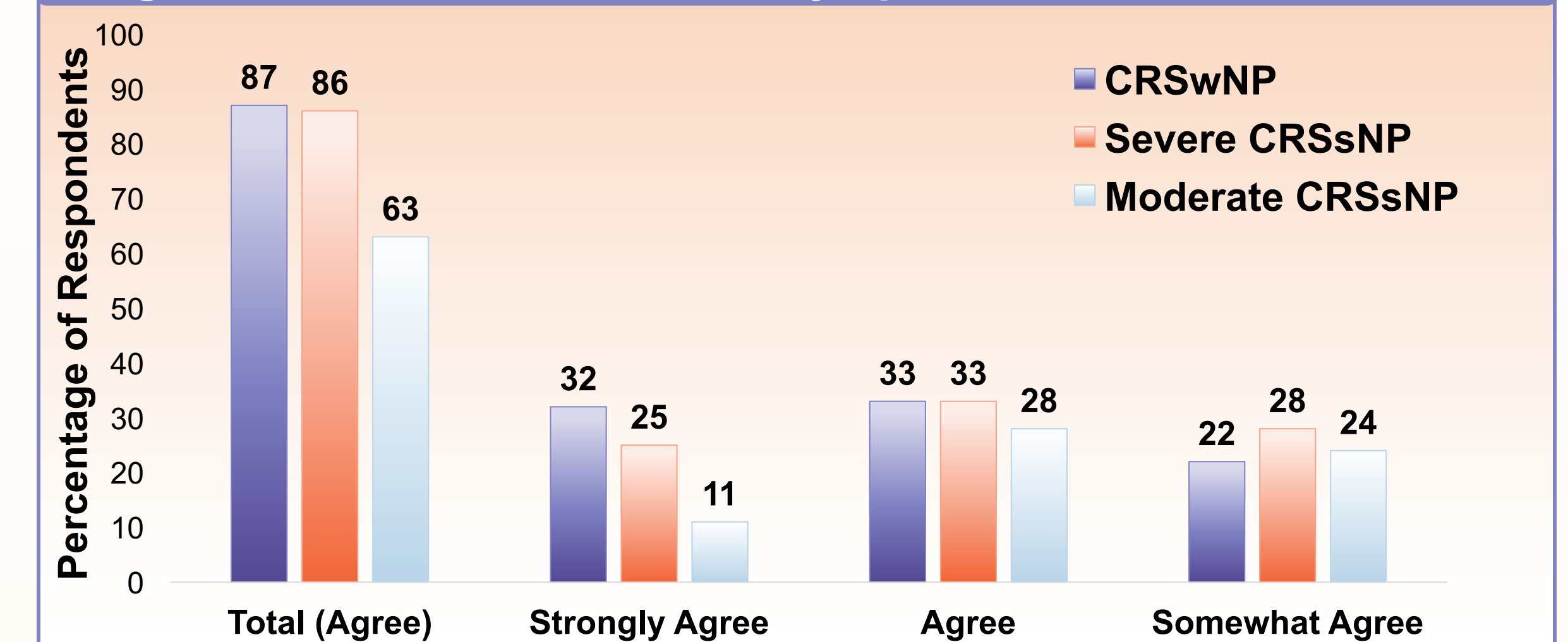
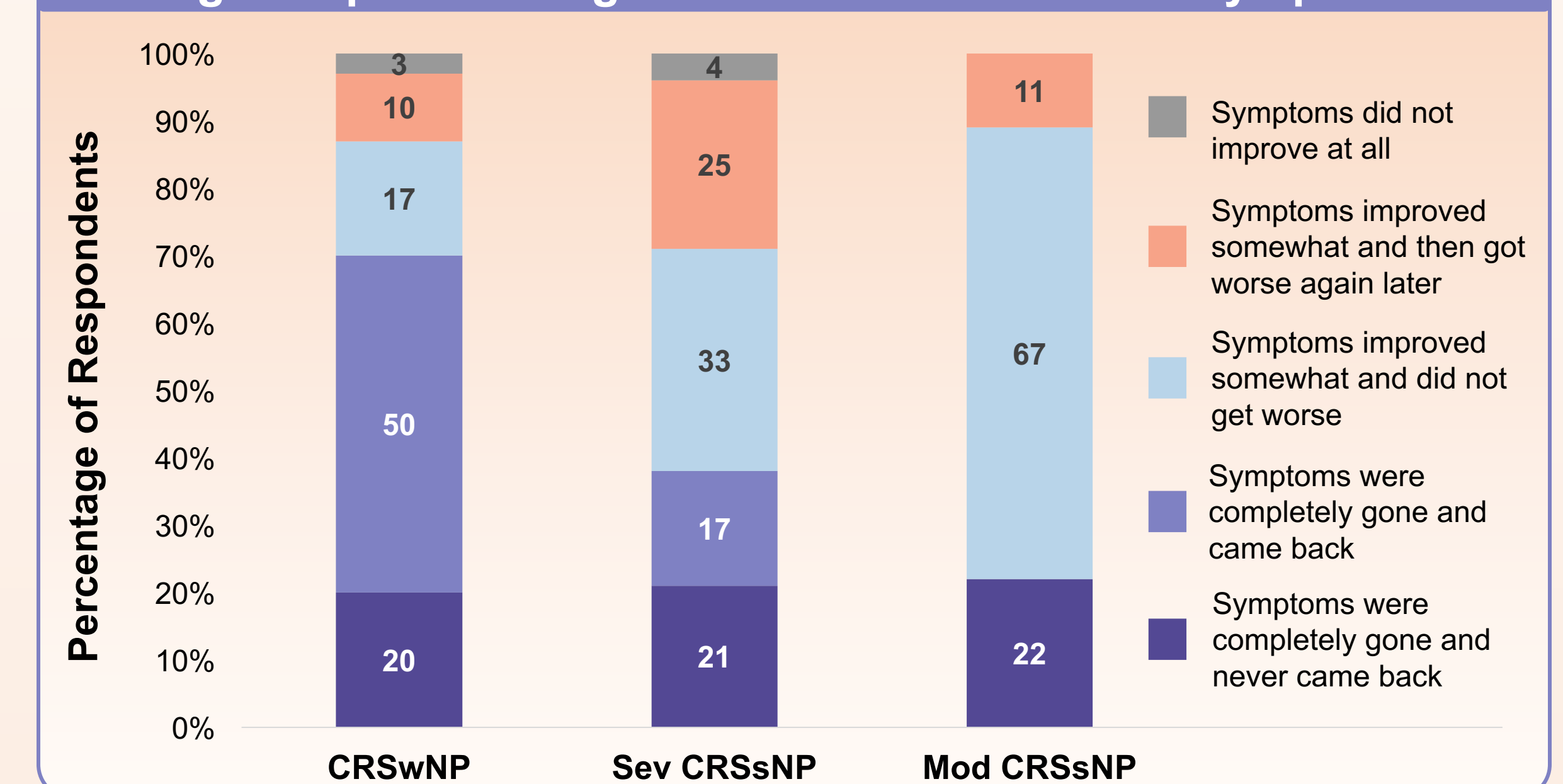


Figure 3. Patients were asked: Please indicate how much you agree or disagree with the following statement: frustrated with symptom relief of current INCS

- Current Nasal Steroid Sprays Not Optimally Tolerated:** Many INCS users report drip out of the nose (38-58%), drip down the throat (43-67%) or dysgeusia (36-43%). CRSwNP and severe CRSsNP patients were *more* bothered by these than other sufferers.
- Surgery Often Helps, but Incompletely:** Among sufferers who had surgery within the past 2 years, few experienced complete symptom relief without recurrence. (Figure 4)

Fig 4. Impact of Surgical Procedures on Nasal Symptoms



- Limitations:** Analyses rely on self-reporting (a strength and a limitation). Objective evidence of disease (endoscopy) and financial data on healthcare use was not available for correlation.

CONCLUSIONS

- This large, population-based representative survey extends our understanding of the burden of illness in people reporting symptoms of CRSwNP and CRSsNP.
- The prevalence of CRS identified in this population-based survey is consistent with estimates reported in the literature.^{4,5}
- A substantial number of individuals who self-reported CRS consider their condition to be severe, and report being severely affected by their symptoms despite frequent medical interventions and multiple available therapies.
- The majority of CRS patients are highly dissatisfied with current INCS therapy, primarily due to inadequate symptom relief, though they also report other problems with current nasal spray delivery methods such as "drip out" and dysgeusia.
- CRS symptoms have a substantial adverse impact, both by QoL and healthcare resource utilization, indicating significant unmet medical need for more and/or better CRS treatment in the broad population.

References:

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- Centers for Disease Control and Prevention. Summary Health Statistics: National Health Interview Survey, 2014. Table A-2.

