Severe asthma patients' characteristics in Mexico versus International Severe Asthma Registry (ISAR) Global

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Rationale and Aim

Rationale

- ISAR global patients have been well characterised in several publications. However, local patients may differ from the global picture, which could in the future result in a different effectiveness and safety profile with biologics

Aim

- To compare pre-biologic initiation data from the Mexican ISAR patients against global
- To compare characteristics among the Mexican patients of:

  (i) Those started on biologic therapy versus non-initiators

  (ii) Ever smokers versus never-smokers.

ISAR: International Severe Asthma Registry

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Methods: Comparing Mexican and Global characteristics in Severe Asthma

- Cross-sectional study among patients with severe asthma. Data was extracted on 25/04/2024. Data was entered prospectively from 2017 as sites joined ISAR. Retrospective data was also entered for some patients visiting sites contributing to ISAR using available medical records.
- Data submitted into the ISAR platform was used. Data from Mexico (n=438) was compared to data globally (n=17,567)
- Index date was defined as the point of biologic initiation or as the first recorded visit following enrolment in ISAR for biologic-naïve patients

- **Inclusion criteria:** Patients aged 18 years or older, with severe asthma (treatment at GINA 2018 step 5 or with uncontrolled asthma at GINA step 4, ie, treated with high-dose inhaled corticosteroid/long-acting β2-agonist) and with data to determine comorbidity status
- **Exclusion criteria:** patients without an index date, age below 18 years or with missing data on age, sex or comorbidities

Variables

Characteristics

- Age
- Sex
- Ethnicity
- Smoking status
- Age at asthma onset
- Asthma duration
- Asthma remission domains: Severe exacerbations, LTOCS use, asthma control, FEV1
- Biomarkers (BEC, IgE, FeNO)
- Biologic Use
- A+E visits and hospitalisations in preceding year
- Allergy tests
- Invasive ventilation

Non-allergic potentially OCS-related comorbidities:

- Obesity
- Osteoporosis
- Diabetes
- Sleep apnoea
- Anxiety and/or Depression
- CVA
- PE and/or VTE
- Peptic Ulcer
- CKD
- Heart Failure
- MI
- Cataract
- Glaucoma
- Pneumonia

Allergy-related comorbidities:

- Allergic Rhinitis
- Chronic Rhinosinusitis
- Nasal Polyposis
- Atopic Dermatitis

ISAR: International Severe Asthma Registry, LTOCS: Long-term Oral Corticosteroid, BEC: Blood Eosinophil Count, IgE: Immunoglobulin E, AR: Allergic Rhinitis, CRS: Chronic Rhinosinusitis, NP: Nasal Polyposis, MI: Myocardial Infarction, CVA:OCS:Oral Corticosteroids, Cerebrovascular Accident, PE: Pulmonary Embolism, VTE: Venous Thromboembolism, CKD: Chronic Kidney Disease, FEV1: Forced Expiratory Volume 1 second, A+E: Accident and Emergency, FeNO: Fractional Exhaled Nitric Oxide, Global Initiative for Asthma, 2018. Global Strategy for Asthma Management and Prevention. [online] Available at: https://ginasthma.org/wp-content/uploads/2018/04/wms-GINA-2018-report-V1.3-002.pdf

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Methods: Comparing Mexican and global characteristics in severe asthma

Study Outcomes:

- Demographic and clinical characteristics calculated for Mexican and ISAR patients
- Prevalence (ever up to index date) of individual comorbidities calculated
- Mexican severe asthma patient analyses: Biologic initiators (n = 276) versus non-biologic initiators (n = 72), and ever smokers (n=43) versus never-smokers (n=296) analysed, within Mexican population only

Statistical analysis:

- Baseline characteristics summarized descriptively
- For the comparison of patients' characteristics in Mexico vs. patients from all other countries in ISAR the Kruskal Wallis test was used for continuous variables and Pearson Chi-squared test was used for categorical variables
- Statistical significance was set at $\alpha = 0.05$ (two-tailed)

ISAR: International Severe Asthma Registry data

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Higher Proportion of Mexican Patients Initiated on Biologics Compared to ISAR

Patient characteristics at index date	ISAR overall (N=16269)		Mexico (n=348)		p-value*
Age (years)	N	%	N	%	<0.001
Mean (SD)	53.48	(15.17)	48.68	(12.92)	
Sex					<0.001
Female: n (%)	10111	(62.15)	273	(78.45)	
Ethnicity, N	14207		341		<0.001
Caucasian: n (%)	10586	(75.47)	11	(3.23)	
North East Asian: n (%)	617	(4.40)	0	(0.00)	
South East Asian: n (%)	840	(5.99)	0	(0.00)	
African: n (%)	389	(2.77)	0	(0.00)	
Mixed: n (%)	336	(2.40)	260	(76.25)	
Other: n (%)	1259	(8.89)	70	(20.53)	
Tobacco use, N	13680		339		<0.001
Current smoker: n (%)	736	(5.38)	4	(1.18)	
Ex-smoker: n (%)	3727	(27.24)	39	(11.50)	
Never smoker: n (%)	9217	(67.38)	296	(87.32)	

Patient characteristics at index date	ISAR overall (N=16269)		Mexico (n=348)		p-value*
Age at asthma onset (years), N	8662		322		0.368
Mean (SD)	31.08	(18.54)	29.93	(16.23)	
Median (Q1, Q3)	31	(15,45)	30	(16,42)	
Asthma duration (years), N	8662		322		0.003
Mean (SD)	21.49	(16.08)	18.76	(14.69)	
Median (Q1, Q3)	18	(8.32)	15	(6.29)	
Biologic initiation					<0.001
Yes: n (%)	7890	(48.50)	276	(79.31)	
Yes/no biologic initiators					
Biologic class in initiators, N	7889		276		<0.001
Anti-IgE: n (%)	3066	(38.86)	203	(73.55)	
Anti-IL5/5R: n (%)	4108	(52.07)	58	(21.01)	
Anti-IL4R alpha: n (%)	705	(8.94)	15	(5.43)	
Anti-TSLP	10	(0.13)	0	(0.00)	

Mexican patients:

- Had higher initiation of biologics (79% vs 49% for ISAR)
- Younger
- Most of mixed (Mexican indigenous-European) ethnicity
- Greater proportion of never smokers
- Greater proportion of females

** P-values compare patients characteristics in Mexico vs. all other countries in ISAR. Kruskal Wallis test was used for continuous variables and Pearson Chi-squared test was used for categorical variables. When only one p-value is provided, it relates to the continuous variable. Ig = immunoglobulin; IL = interleukin; ISAR = international severe asthma registry; Q = Quartile; R = receptor; SD = standard deviation; TSLP = Thymic stromal lymphopoietin*

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Mexican severe asthma patients had a higher prevalence of allergic sensitization (66.9 versus 80.1%, p<0.001)

Biomarker data of the global and Mexican ISAR patients

Biomarkers	ISAR overall		Mexico		p-value*
	(N=16.269)		(n=348)		
	N	%	N	%	
Highest blood eosinophil count (cells/mcL), N	10.211		202		NS
Mean (SD)	521	(635)	467	(414)	
Median (Q1, Q3)	350	(196,670)	395	(220,609)	
300+: n (%)	6.109	(59.83)	127	(62.87)	
Eosinophilic gradient, N	10.071		206		NS
Unlikely/noneosinophilic: n (%)	61	(0.61)	0	(0.00)	
Least likely: n (%)	673	(6.68)	13	(6.31)	
Likely: n (%)	959	(9.52)	27	(13.11)	
Most likely: n (%)	8.378	(83.19)	166	(80.58)	
Latest FeNO concentration (ppb), N	6.847		100		<0.001
Mean (SD)	44	(46)	48	(42)	
Median (Q1, Q3)	27	(14,56)	34	(26,56)	
Latest serum total IgE concentration (IU/mL), N	9.099		199		0.017
Mean (SD)	441	(1299)	382	(563)	
Median (Q1, Q3)	148	(47,412)	193	(76,443)	

Biomarkers	ISAR overall		Mexico		p-value*
	(N=16.269)		(n=348)		
	N	%	N	%	
Allergen test results					
Any, N	8.236		307		<0.001
Positive: n (%)	5.511	(66.91)	248	(80.78)	
House dust mites, N	8.236		307		<0.001
Positive: n (%)	2.918	(35.43)	195	(63.52)	
Pollen, N	8.236		307		0.198
Positive: n (%)	4.145	(50.33)	166	(54.07)	
Animal hair, N	8.236		307		0.045
Positive: n (%)	1.906	(23.14)	56	(18.24)	
Mould, N	8.236		307		<0.001
Positive: n (%)	1.117	(25.30)	25	(8.14)	
Food, N	5.936		302		<0.001
Positive: n (%)	848	(14.29)	12	(3.97)	

** P-values compare patients characteristics in Mexico vs. all other countries in ISAR. Kruskal Wallis test was used for continuous variables and Pearson Chi-squared test was used for categorical variables. When only one p-value is provided, it relates to the continuous variable. ISAR = international severe asthma registry; Q = Quartile; SD = standard deviation*

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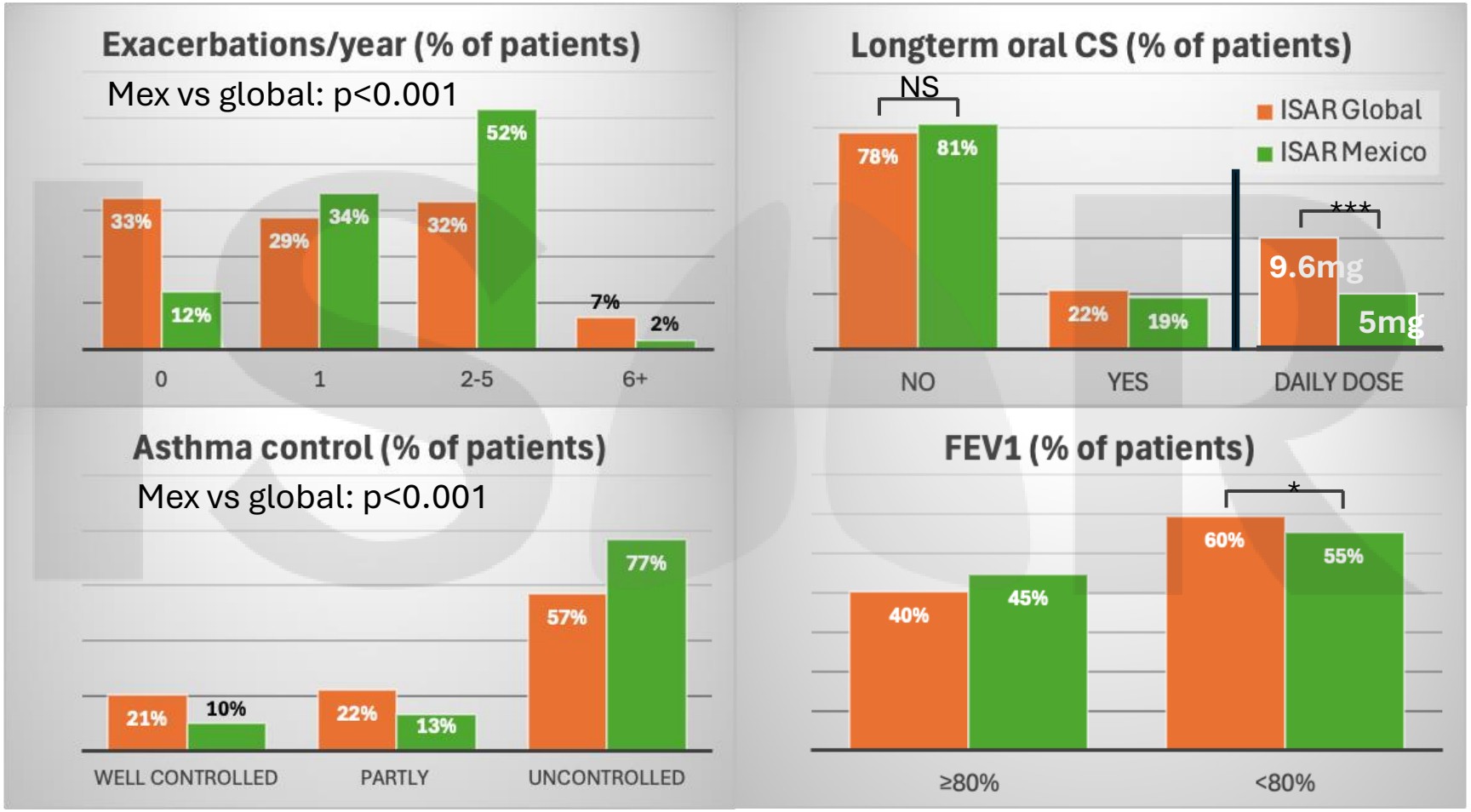
Mexican patients had more asthma exacerbations, worse asthma control, but better lung-function and lower long-term oral corticosteroid (LTOCS) dose

Comparison of the four domains of remission among Mexican and Global ISAR patients



*Mexican ISAR patients have a higher frequency of severe exacerbations, equally frequent use of long-term oral corticosteroids (LTOCS) be it at a lower dose, worse asthma control but less frequent lung function deterioration. * = p<0.05; *** = p<0.001*
CS = corticosteroids; FEV1 = Forced Expiratory Volume in one second; Mex = Mexican patients; NS = not significant.

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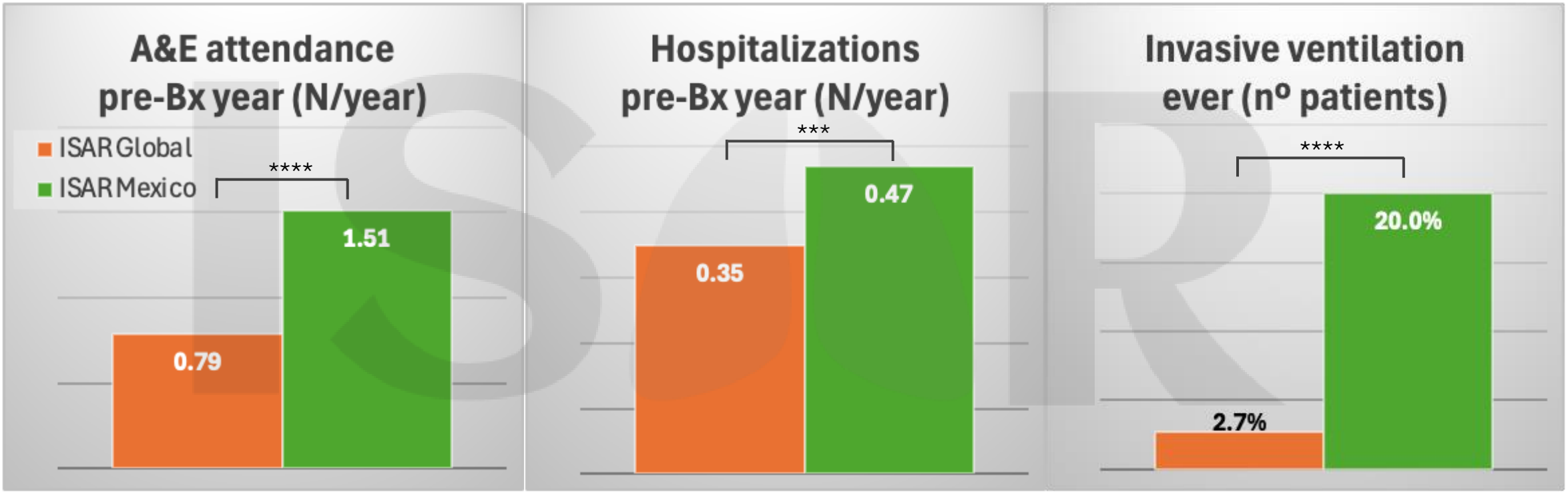
All exacerbation parameters were more frequent among Mexican severe asthma patients

Parameters of severe exacerbations in Mexican versus Global ISAR patients



ISAR: International Severe Asthma Registry, A&E: Accident and Emergency, Bx: Biologic therapy, *** = p<0.001**** = *p<0.0001. nº = number of*

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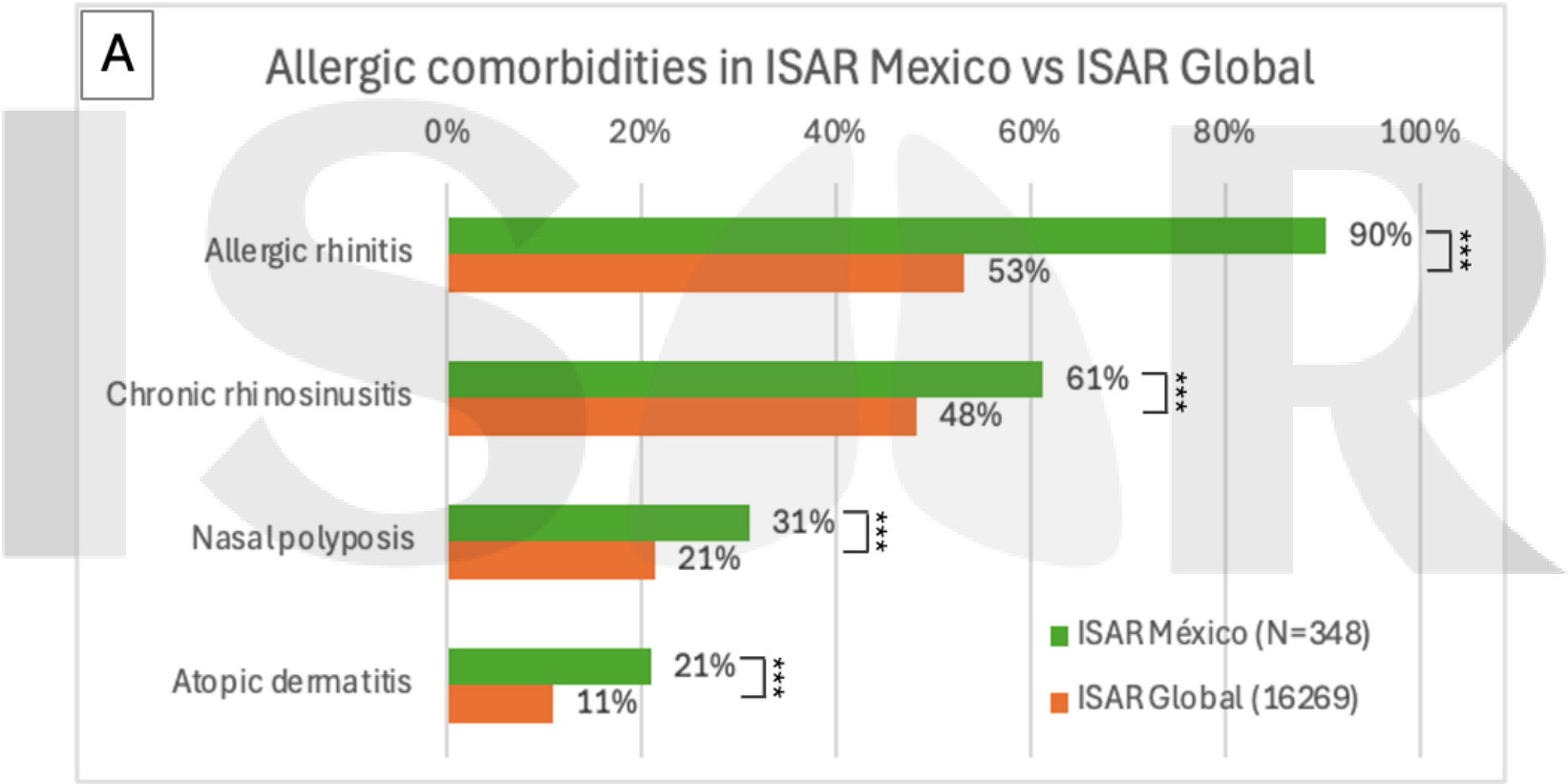
All allergic comorbidities were more frequent in the Mexican patients

Frequency of allergic comorbidities in ISAR Mexico versus ISAR Global patients in general (A)



ISAR: International Severe Asthma Registry, *** = p<0.001

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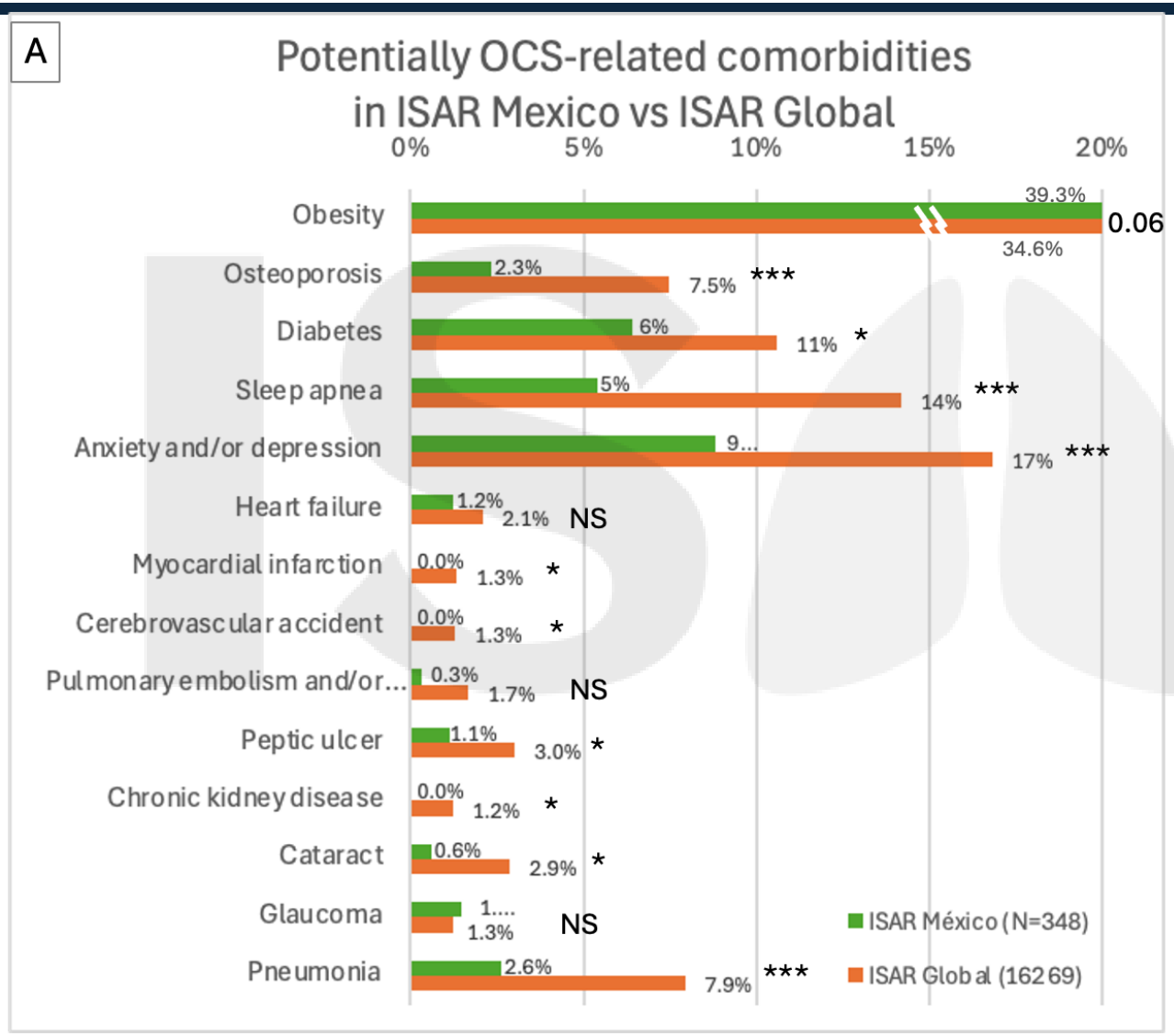
Almost all non-allergic potentially OCS related comorbidities more frequent among the global patients than Mexico severe asthma patients



Obesity is an exception, as there is a trend for a higher prevalence of this among the Mexican ISAR patients group

ISAR: International Severe Asthma Registry, * = p<0.05 *** = p<0.001; NS = not significant, OCS: Oral Corticosteroids

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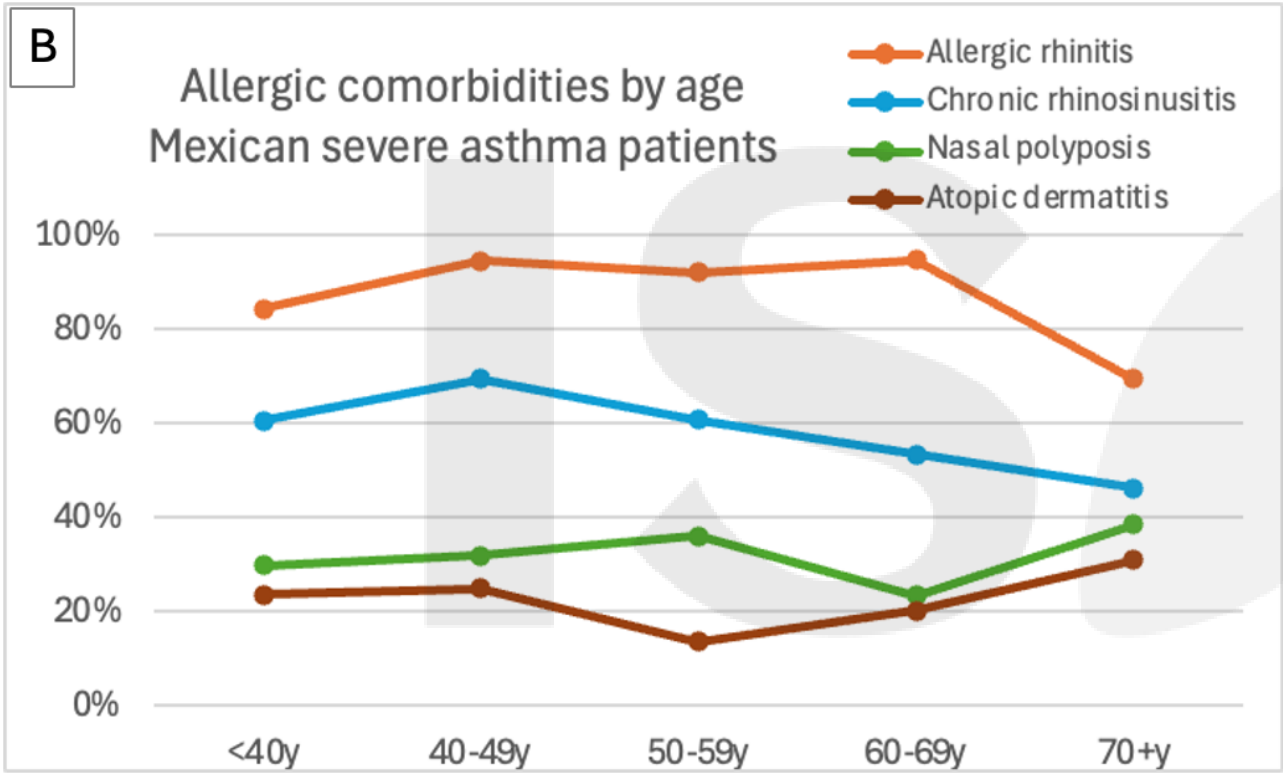
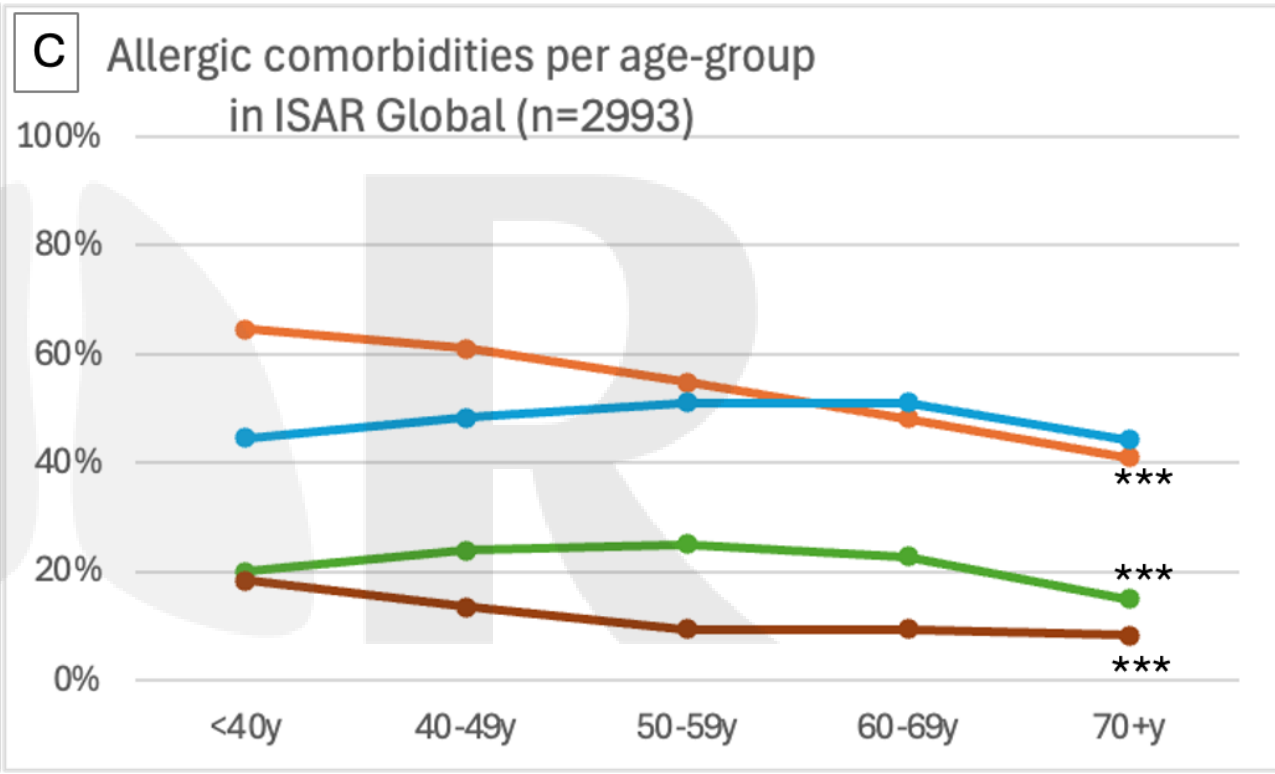
Trend of reduction with increasing age for allergic rhinitis and chronic rhinosinusitis in Mexican patients

Frequency of allergic comorbidities in ISAR Mexico versus ISAR Global patients per age-group in ISAR Mexico (B) and ISAR Global (C)





For Mexican patients: trend of reduction with increasing age for allergic rhinitis and chronic rhinosinusitis, while nasal polyps and atopic dermatitis seem to augment in prevalence with increasing age, none reaching significance. Global ISAR group: reduced prevalence with age for all, but CRS.

ISAR: International Severe Asthma Registry, *** = p<0.001;

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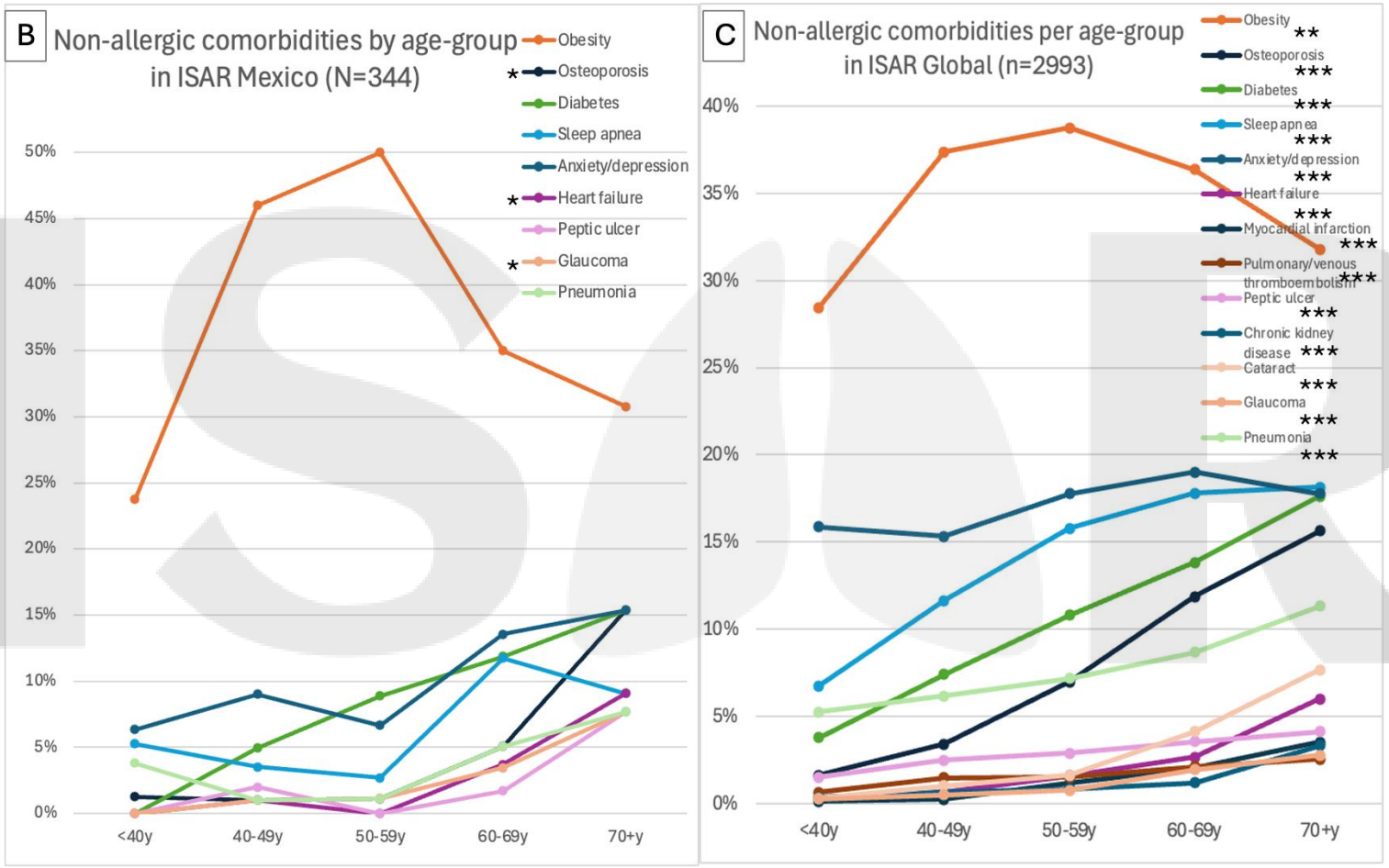
Almost all non-allergic potentially OCS-related comorbidities increase with age in both the Mexican ISAR patients and in ISAR global



Frequency of non-allergic comorbidities in ISAR Mexico versus ISAR Global patients per age-group in ISAR Mexico (B) and ISAR Global (C).

Obesity is the exception, peaking in the 50-59y age-category of severe asthma patients.

ISAR: International Severe Asthma Registry, OCS: Oral Corticosteroids* = p<0.05, ** = p<0.01 *** = p<0.001; NS = not significant

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Among Mexican patients only:

Biologic initiators have higher frequency asthma exacerbations, later age asthma onset

Ever smokers have more uncontrolled asthma, higher FeNO, greater prevalence comorbidities

Biologic initiators compared to the non-initiators were/had:

- Younger
- More female (82%)
- Greater proportion with obesity
- **Later age-of-asthma-onset and shorter asthma duration**
- **Higher frequency of asthma exacerbations**
- Lower number of LTOCS users
- Inflammation is more likely eosinophilic, but equally high frequency allergic sensitization
- Less sleep apnea and anxiety/depression

Severe asthma ever smokers, compared to never smokers had:

- **More uncontrolled asthma**
- Slightly lower frequency of severe exacerbations, A&E attendances, hospital admissions and invasive ventilation
- **FeNO almost twice as high**
- **All T2 comorbidities more frequently**, particularly CRS, NP and AD
- Greater prevalences of obesity, diabetes (19 vs 4.8%) and history of embolism

ISAR: International Severe Asthma Registry, LTOCS: Long-term Oral Corticosteroids, FeNO: Fractional Exhaled Nitric Oxide, CRS:Chronic Rhinosinusitis, NP: Nasap polyps, AD: Atopic Dermatitis, A&E: Accident and Emergency

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Key findings and clinical implications

Mexican patients compared to Global ISAR patients (at biologic initiation or at enrolment to ISAR if biologic naïve):

Patient Profile:

- Younger age
- Shorter duration asthma
- Greater allergic comorbidities
- Fewer non-allergic potentially OCS-related comorbidities

Disease Severity and therapy:

- Poorer asthma control
- More exacerbations
- Better lung function
- Lower LTOCS dose
- Greater biologic use (79% vs <50%)

Clinical Implications:

- Mexican patients strong candidates for biologic therapy

Management Goals:

- Reduce exacerbations & improve control
- Optimise inhalers, prompt initiation of biologics

ISAR: International Severe Asthma Registry, OCS: Oral Corticosteroids, LTOCS:Long-term Oral Corticosteroids

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