



Association of easier biologic access with remission and other clinical outcomes in severe asthma: a global real-world study: **GLEAM II**



Association of easier biologic access with remission and other clinical outcomes in severe asthma: a global real-world study

Susanne Hansen, Ming-Ju Tsai, Trung N. Tran, John D. Blakey, Benjamin Emmanuel, Shawn D. Aaron, Yahya Habis, Valeria Perugini, Alan Altraja, Rohit K. Katial, Luis Perez-de-Llano, Paul E. Pfeffer, Nikolaos G. Papadopoulos, John Townend, Ghislaine Scelo, Aaron Beastall, Lakmini Bulathsinhala, John Busby, Andrew W. Lindsley, Wendy C. Moore, Reynold A. Panettieri Jr., Giorgio Walter Canonica, Enrico Heffler, Cristina Cardini, Giuseppe Guida, Celeste M. Porsbjerg, Anne-Sofie Bjerrum, Anna Von Bülow, Ole Hilberg, Kjell Erik Julius Håkansson, Marianne Baastrup Soendergaard, Charlotte Suppli Ulrik, Eileen Wang, Michael E. Wechsler, Nicholas Chapman, Flavia C. L. Hoyte, Kanao Otsu, Liam G. Heaney, David J. Jackson, Pujan H. Patel, Dermot Ryan, Celine Bergeron, Shelley Abercromby, Mohit Bhutani, Kenneth R. Chapman, Andréanne Côté, Beth E. Davis, Delbert R. Dorscheid, Leiana Hoshryari, Brianne Philipenko, Hana Serajeddini, Florence Schleich, Renaud Louis, Piotr Kuna, Borja G. Cosío, Désirée Larenas-Linnemann, Carlos A. Torres-Duque, María José Fernández-Sánchez, Elizabeth Garcia, Fabio Bolívar-Grimaldos, Libardo Jiménez-Maldonado, Diana Jimena Cano-Rosales, Ivan Solarte, Riyadh Al-Lehebi, Adeeb A. Bulkhi, Mona Al-Ahmad, Takashi Iwanaga, Soichiro Hozawa, Hisako Matsumoto, Tatsuya Nagano, Tomoko Tajiri, Bernt Bøgvald Aarli, Diahn-Warng Perng, Yi-Han Hsiao, Pin-Kuei Fu, Chau-Chyun Sheu, Konstantinos Kostikas, Mina Gaga, Athena Gogali, Maria Kallieri, Stelios Loukides, Michael Makris, Maria Dimosthenis Ntakoula, Andriana I. Papaioannou, Giannis Paraskevopoulos, Fotios Psarros, Bassam Mahboub, Laila Salameh, Mariko Siyue Koh, Mei Fong Liew, Pee Hwee Pang, Tze Lee Tan, Tunn Ren Tay, Paulo Márcio Pitrez, Chin Kook Rhee, Njira Lugogo, Arjun Mohan, João A. Fonseca, Ana Alves da Silva, Cláudia Chaves Loureiro, Hadassa Cristhina de Azevedo Soares dos Santos, Jorge Fernando Máspero, Ledit R. F. Arduoso, María Eugenia Franchi, Martin Sivori, Ana María Stok, Anahí Yañez, George Christoff, Todor A. Popov, Patrick D. Mitchell, Sundeep Santosh Salvi, Richard W. Costello, Eve Denton, Mark Hew, Christine R. Jenkins, David Langton, Peter G. Middleton, Matthew J. Peters, Lauri Lehtimäki, Arnaud Bourdin, Camille Taillé, Christian Taube, Zsuzsanna Csoma, Dóra Lúdvíksdóttir, Job F.M. van Boven, James Fingleton, Leif Bjerner, Helena Emery, Graham Lough, Roy Alton Pleasants, Diego J. Maselli, Christopher S. Ambrose, Cathy Emmas, Andrew N. Menzies-Gow, Victoria Carter, Nevaashni Eleangovan, Ruth B. Murray, Chris A. Price, Mohsen Sadatsafavi, and David B. Price, FRCGP

Rationale

Time to biologic initiation for the treatment of severe asthma (SA) is affected by many factors, including ease of access to biologics, which is often subject to regulatory approval and reimbursement criteria.

Research question

Does the ease of biologic access (using BACS as a proxy) affect post-biologic asthma outcomes, including remission?

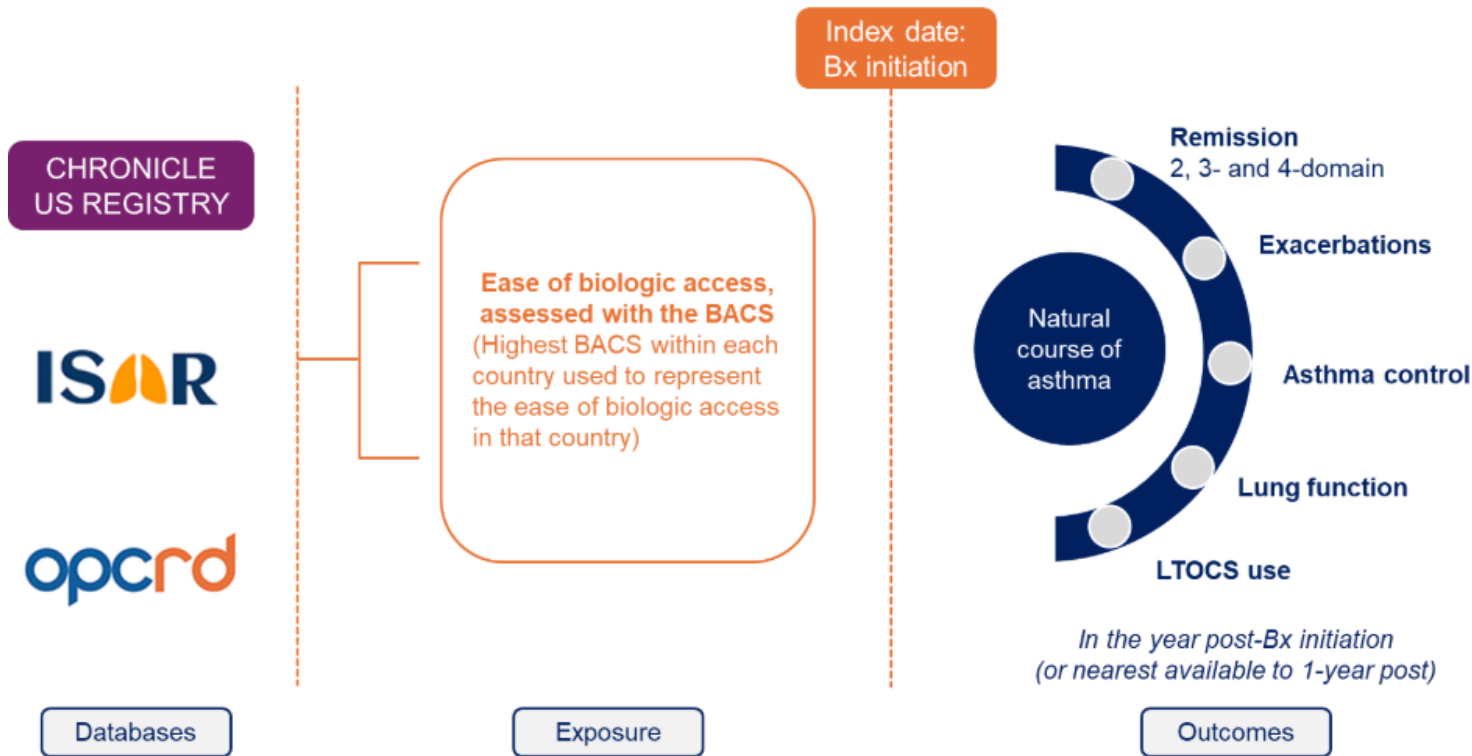
Methods

- Ecological study using data from the CHRONICLE US SA registry, ISAR, and the UK Optimum Patient Care Research Database, together comprising data from 21 countries
- Associations between BACS and the proportion of patients with a favorable asthma outcome 1-year post-biologic were tested.
- Several definitions of favorable outcome were used, including proportion of patients who achieved clinical remission*, experienced no exacerbations, had well- or partly controlled asthma, ppFEV1 or ppPEFR $\geq 80\%$, and no LTOCS use.

*Defined using 2, 3 and 4 domains

BACS: Biologic accessibility score – composition score of prescription criteria for biologics in severe asthma; ISAR: International Severe Asthma Registry; LTOCS = Long-term oral corticosteroids; ppFEV1 = Percent predicted forced expiratory volume in 1 second; ppPEFR = Percent predicted peak expiratory flow rate; SA: Severe asthma
Hansen, S. et al. Association of easier biologic access with remission and other clinical outcomes in severe asthma: a global real-world study, *J Asthma Allergy*. In press

Study Design



Subject disposition

Data source	CHRONICLE (N=3,020)	ISAR (N=12,220)	OPCRD (N=1,223)	Total (N=16,463)
Sequential exclusions				
 Missing biologic initiation date	10 (0.3)	1,248 (10.2)	0 (0.0)	1,258 (7.6)
 Missing age	2 (0.1)	41 (0.3)	0 (0.0)	43 (0.3)
 Age <18 years	33 (1.1)	271 (2.2)	43 (3.5)	347 (2.1)
 Missing sex	0 (0.0)	3 (0.0)	2 (0.2)	5 (0.0)
 BACS not assessed or no recognised access criteria for the biologic initiated	79 (2.6)	1,485 (12.0)	197 (18.1)	1,741 (10.6)
 First biologic initiated after 2022	113 (3.7)	1,182 (9.7)	268 (21.9)	1,563 (9.5)
 No outcomes data available*	10 (0.3)	2,289 (18.7)	24 (2.0)	2,323 (14.1)
 Included, n (%)	2,773 (91.8)	5,721 (46.8)	689 (56.3)	9,183 (55.8)

International Severe Asthma Registry, ISAR, OPCRD: Optimum Patient Care Research Database, BACS: biologic accessibility score

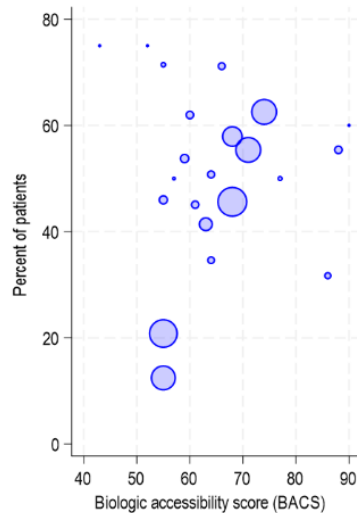
All data are presented as n (%), *Patients, who did not have data available for any of the outcomes of interest in this study

Hansen, S. et al. Association of easier biologic access with remission and other clinical outcomes in severe asthma: a global real-world study, *J Asthma Allergy*. In press

Higher BACS was associated with a higher probability of achieving remission

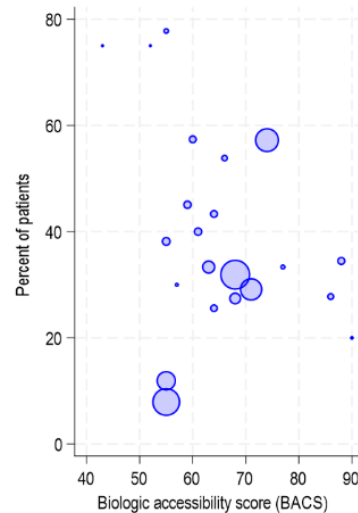
**A: 2-domain remission
(LTOCS + exacerbations)**

N=22, $r=0.81$, $P<0.001$



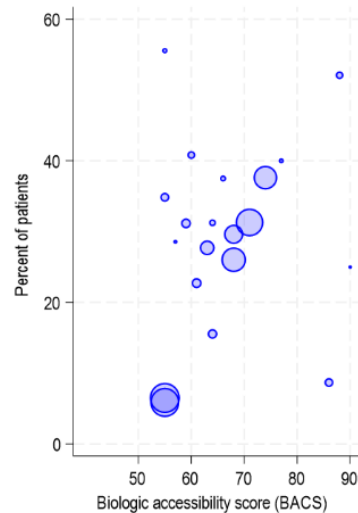
**B: 3-domain remission
(2-domain + control)**

N=22, $r=0.67$, $P=0.001$



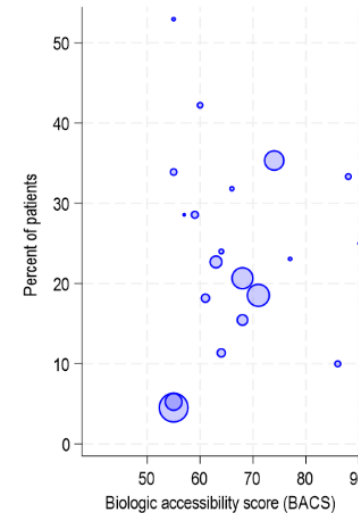
**C: 3-domain remission
(2-domain + lung function)**

N=20, $r=0.81$, $P<0.001$



**D: 4-domain remission
(2-domain + control +
Lung function)**

N=20, $r=0.71$, $P<0.001$



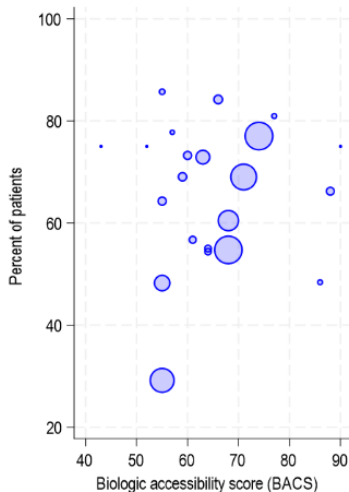
LTOCS: Long-term Oral Corticosteroids. Points represent individual countries or data sources with size of the circle indicating precision of the result for that country.

Hansen, S. et al. Association of easier biologic access with remission and other clinical outcomes in severe asthma: a global real-world study, *J Asthma Allergy*. In press

Higher BACS was strongly correlated with no exacerbations 1 year post-biologic initiation

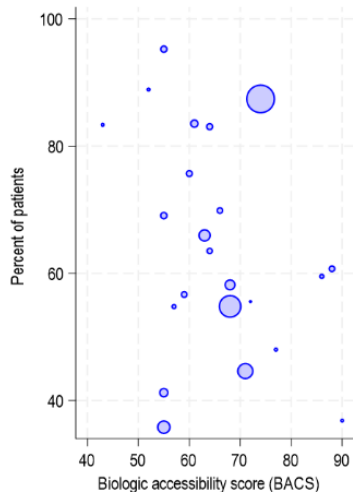
A: Zero exacerbations

N=22, $r=0.68$, $P<0.001$



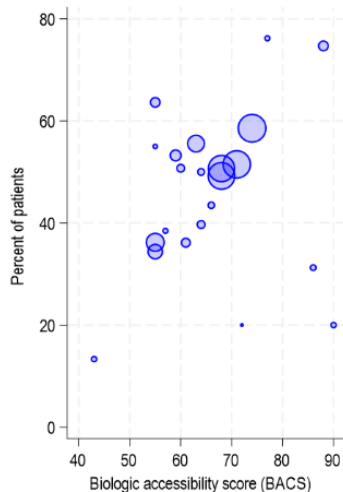
**B: well- or partly-
Controlled asthma**

N=23, $r=0.42$, $P=0.047$



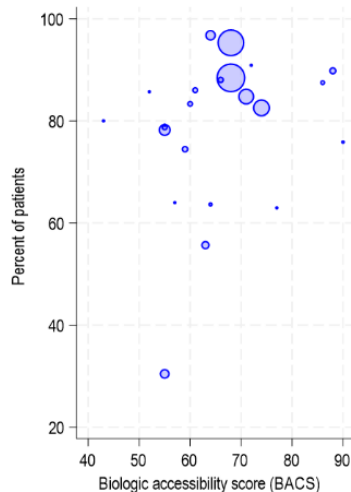
C: ppFEV₁ or ppPEFR $\geq$ 80%

N=22, $r=0.58$, $P=0.004$



D: LTOCS non-user

N=23, $r=0.42$, $P=0.045$



1 year post biologic therapy, higher BACS was:

Strongly correlated with:

- **No exacerbations**

Moderately correlated with:

- **Absence of lung function impairment**
- **Having well- or partly controlled asthma**
- **Non-use of LTOCS**

LTOCS: Long-term Oral Corticosteroids, ppFEV₁: percent predicted forced expiratory volume in one second, ppPEFR: percent predicted peak expiratory flow rate. Points represent individual countries or data sources with size of the circle indicating precision of the result for that country.

Hansen, S. et al. Association of easier biologic access with remission and other clinical outcomes in severe asthma: a global real-world study, *J Asthma Allergy*. In press

Summary: Easier access to biologics in severe asthma is associated with higher likelihood of remission and improved clinical outcomes



Greater biologic accessibility (BACS) was consistently associated with a **higher likelihood of achieving clinical remission**, including across 2-, 3-, and 4-domain definitions.



Greater biologic accessibility was associated with:



fewer
severe
exacerbations



better
asthma
control



better
lung
function



reduced
long-term oral
corticosteroid
use

1 year after biologic initiation.

IMPLICATIONS FOR CLINICAL PRACTICE



These findings suggest that **improving access to biologic therapies** may help patients **receive treatment earlier**, increasing the likelihood of **achieving remission** and **other favourable clinical outcomes**.



The findings support efforts to:



improve equitable
access to biologics



simplify eligibility
pathways where appropriate



reduce delays
to biologic initiation

to help patients realise the full therapeutic potential of biologic treatment.

Easier access to biologics is associated with greater likelihood of remission and better outcomes in severe asthma

Real-world study across 21 countries shows that greater biologic accessibility leads to earlier treatment and significantly better outcomes one year after initiation.

