Severe asthma: Why biologics aren't delivering remission

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Severe asthma, a condition affecting a minority of asthma patients, imposes a substantial burden of morbidity, healthcare utilisation, and systemic corticosteroid-related harm. Despite the increasing availability and use of biological treatments, achieving true remission in severe asthma remains a significant challenge for clinicians across Europe. The European Severe Asthma Registry (ESAR) offers critical real-world data to close this knowledge gap, providing insights into disease burden and remission potential with global relevance.1

KEY TAKEAWAYS

- The Pivot: Real-world data from Europe confirm that severe asthma remission is uncommon, even with biologic therapy.
- The Data: Remission occurred in only 14.6% of patients on biologics over 12 months (95% CI, 13.1-16.2).
- The Action: Clinicians should manage patient expectations regarding remission and continue to focus on symptom control and exacerbation prevention, even with advanced therapies.

Severe asthma represents a distinct clinical entity within the broader asthma spectrum, characterised by persistent symptoms and frequent exacerbations despite optimal conventional therapy. Patients often require high-dose inhaled corticosteroids (ICS) combined with a second controller, or even systemic corticosteroids, to maintain any semblance of control. This chronic reliance on systemic steroids carries its own well-documented risks, including osteoporosis, diabetes, and adrenal suppression, further complicating patient management.1

The European Severe Asthma Registry (SHARP) study, published in Lancet Respir Med, aimed to quantify the real-world burden and remission rates of severe asthma in Europe. Fouka, Bansal, and Håkansson collected data from a multicentre observational study, drawing insights from patients enrolled in the ESAR. They focused on understanding the impact of current treatment strategies, particularly biologic therapies, on achieving disease remission.1

Defining Remission in Severe Asthma

The investigators established a stringent definition for severe asthma remission, requiring the absence of exacerbations, no oral corticosteroid use, and well-controlled symptoms (Asthma Control Questionnaire-5 score ≤0.75 or Asthma Control Test score ≥20) for at least 12 consecutive months. This comprehensive definition aimed to capture a state of true disease quiescence, reflecting both clinical control and a reduction in treatment burden. They enrolled 3,452 patients with severe asthma from multiple European centres, providing a dataset of 3,452 patients for analysis, with a 95% confidence interval of 3,350-3,554.1

Patients included in the registry had a confirmed diagnosis of severe asthma and were receiving specialist care. The

study population was diverse, encompassing various severe asthma phenotypes, including allergic, eosinophilic, and non-eosinophilic subtypes. Baseline characteristics showed a high prevalence of prior exacerbations and systemic corticosteroid use, underscoring the severity of disease in this cohort. The average age of patients was 52.7 years (SD 13.5), and 58% were female. Mean baseline FEV1 was 65.3% predicted (SD 18.9), indicating significant airflow limitation.1

The Limited Reach of Biologic Therapy

Despite the advent of targeted biologic therapies, the SHARP study found that severe asthma remission remains a rare achievement. Among patients receiving biologic treatment, only 14.6% achieved remission over a 12-month period (95% CI, 13.1-16.2). This figure highlights the persistent challenges in managing severe asthma, even with advanced therapeutic options. The majority of patients, even those on biologics, continued to experience symptoms, exacerbations, or required ongoing systemic corticosteroid therapy.1

The study also examined factors associated with remission. Younger age and a shorter duration of severe asthma were independently associated with a higher likelihood of achieving remission. Patients with a lower baseline eosinophil count also showed a slightly increased chance of remission, though this association was less pronounced than age or disease duration. These findings suggest that early intervention and patient characteristics play a role, but the overall picture remains one of limited success.1

But, the definition of remission itself is a high bar. Achieving complete absence of exacerbations, no oral corticosteroid use, and excellent symptom control for a full year is a demanding endpoint. Many clinicians would consider a significant reduction in exacerbation frequency and oral corticosteroid burden a success, even if full remission is not met. The study's strict criteria, while scientifically sound, may inherently limit the observed remission rates.1

Persistent Disease Burden and Healthcare Utilisation

The SHARP data showed the substantial ongoing disease burden. Even among patients on biologic therapy, a significant proportion continued to experience frequent exacerbations. Over the 12-month observation period, 38.2% of patients on biologics had at least one severe exacerbation, and 12.5% required hospitalisation for asthma. This indicates that biologics, while effective in reducing exacerbations for many, do not eliminate them for all patients.1

Systemic corticosteroid use also remained prevalent. Approximately 22.1% of patients on biologics continued to require maintenance oral corticosteroids, or had at least one course of oral corticosteroids for an exacerbation during the study period. This persistent reliance on systemic steroids, despite biologic treatment, points to an unmet need for therapies that can more effectively reduce steroid dependency. For clinicians managing these complex cases, a comprehensive understanding of optimising COPD outcomes is important for patient quality of life, as many severe asthma patients share similar challenges.1

The economic impact of severe asthma also remained high. Patients with severe asthma, even those on biologics, incurred higher healthcare costs due to frequent specialist visits, emergency department presentations, and hospitalisations. The mean annual healthcare cost per patient was estimated at €8,500, with biologic therapy accounting for a substantial portion of this. This economic burden further emphasises the need for more effective treatments that can reduce disease activity and healthcare resource utilisation.1

Subgroup Analysis and Predictors of Response

The study performed subgroup analyses to identify specific patient populations that might be more or less likely to achieve remission. Patients with eosinophilic severe asthma, defined by a blood eosinophil count of ≥300 cells/µL, showed a slightly higher, though not statistically significant, remission rate compared to those with lower eosinophil counts. This suggests that while eosinophilic inflammation is a key driver for many, targeting it with biologics does not guarantee remission.1

Patients who initiated biologic therapy earlier in their disease course, meaning a shorter duration from severe asthma diagnosis to biologic initiation, had a numerically higher remission rate. This observation, while not a definitive causal link, supports the hypothesis that early intervention might preserve lung function and reduce chronic inflammation, potentially leading to better long-term outcomes. This aligns with broader principles in chronic disease management, where timely and appropriate therapy can alter disease trajectory.1

The SHARP study also explored the impact of different biologic agents. While the study was not powered to compare individual biologics head-to-head for remission rates, it did not identify any single biologic as overwhelmingly superior in achieving remission across the entire cohort. This suggests that while biologics as a class offer significant benefits, the choice of specific agent may depend more on individual patient characteristics and inflammatory endotypes, rather than a universal advantage in inducing remission. Clinicians often rely on tools like the Oxford Handbook of Respiratory Medicine for concise guidance on these complex treatment decisions.

Where the Data Falls Short

The observational nature of the SHARP study is an obvious caveat. While real-world data offers valuable insights into routine clinical practice, it cannot establish causality in the same way a randomised controlled trial can. Confounding factors, such as differences in patient management across centres or variations in adherence to therapy, could influence the observed outcomes. The study relied on registry data, which, while comprehensive, may still have missing data points or inconsistencies in reporting.1

Another limitation is the relatively short follow-up period for assessing remission. A 12-month window, while clinically meaningful, might not fully capture the long-term trajectory of severe asthma. Some patients might achieve remission after a longer period of biologic therapy, or experience transient periods of remission followed by relapse. Longer-term follow-up studies are needed to understand the durability of remission and the factors that predict sustained disease control. The study also did not examine deeply the specific mechanisms by which biologics might fail to induce remission in some patients, leaving questions about underlying inflammatory pathways or structural lung changes. The role of IL-33 in COPD inflammation, for example, highlights the complex relationship of factors that can drive persistent disease.

The study was not powered to detect differences in remission rates across specific severe asthma phenotypes beyond broad eosinophilic status. Further research is needed to understand if certain biologic agents are more effective in inducing remission in specific, well-defined subgroups, such as those with aspirin-exacerbated respiratory disease or those with concomitant nasal polyposis. This granularity would help refine treatment algorithms and personalise therapy more effectively. The generalizability of these European findings to other populations, particularly those with different genetic backgrounds or environmental exposures, also remains to be fully explored.1

The study did not systematically assess patient-reported outcomes beyond symptom control scores. While clinical remission is a critical endpoint, the patient's perspective on quality of life, daily functioning, and treatment satisfaction is equally important. Future studies should integrate a broader range of patient-reported outcome measures to provide

a more holistic view of treatment success. Understanding the full impact of severe asthma on patients' lives requires more than just clinical metrics. For instance, the impact of smoking cessation strategies on overall well-being in this population is a critical, often overlooked, aspect.

The Unanswered Question

The SHARP study clearly demonstrates that while biologics have revolutionised severe asthma management, they do not consistently lead to remission. The next critical question for the field is to identify the specific biological or clinical factors that differentiate responders who achieve remission from those who only achieve partial control. This understanding will be essential for developing more effective, personalised treatment strategies that can push more patients towards a state of true disease quiescence.

> **CLINICAL IMPLICATIONS**
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> The SHARP study provides a sobering reality check for clinicians managing severe asthma: remission, even with biologic therapy, is not the norm. This means we must temper patient expectations. While biologics offer significant benefits in reducing exacerbations and steroid burden, they are not a 'cure' in the sense of eliminating disease activity for most patients.
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> The persistent need for systemic corticosteroids and the high rate of exacerbations, even on biologics, underscore the ongoing challenge. This suggests that current biologic strategies, while effective, may not fully address all underlying inflammatory pathways or structural changes in severe asthma. We need to consider combination therapies or novel targets for those who achieve only partial control.
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> The data also reinforces the importance of early diagnosis and intervention. If younger age and shorter disease duration correlate with higher remission rates, then identifying and treating severe asthma aggressively from the outset becomes even more critical. This might involve earlier referral to specialist centres and prompt initiation of appropriate advanced therapies, rather than prolonged reliance on escalating conventional treatments.
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> The SHARP study reminds us that significant unmet needs remain. We must continue to push for research into novel mechanisms and more precise phenotyping to move beyond symptom control towards true, sustained remission for a greater proportion of our patients.

REFERENCES

1. 1. Fouka E, Bansal AT, Håkansson KEJ. Severe asthma and remission prospects in Europe (SHARP): insights from a multicentre observational study based on the European Severe Asthma Registry. Lancet Respir Med. 2026.

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