Efficacy assessment and key predictors of therapeutic response to biological treatment of severe asthma.

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Introduction

Relying on a single global measure of disease control does not fully reflect the heterogeneous response to biological treatment. Therefore, the assessment of therapeutic response based on relevant composite measures is gaining more attention with the introduction of biologics.
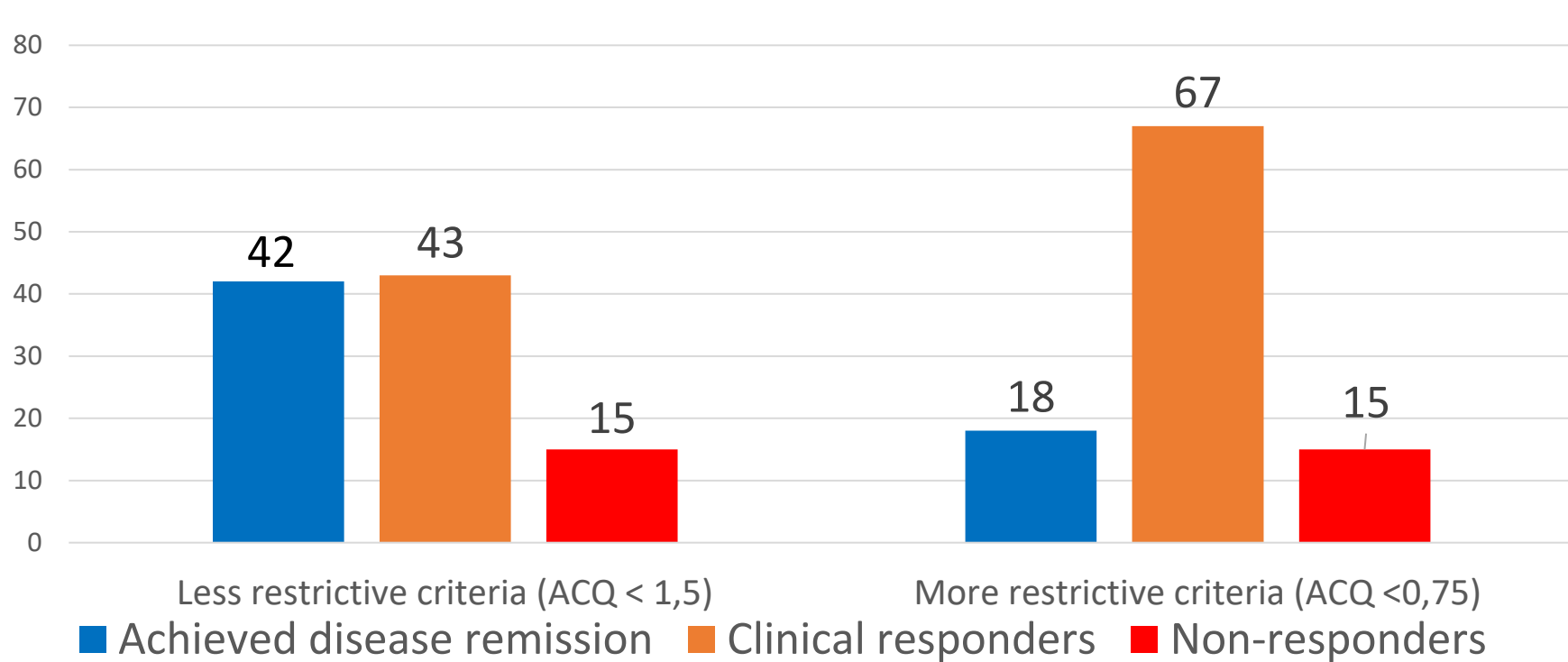
The choice of the specific biological therapy depends on the phenotype and endotype of the disease, which results from the selective blocking of inflammatory pathways by these drugs. Even though several biomarkers have been explored in asthmatic patients with T2 severe asthma, there is still a gap in their feasibility in clinical practice and there is a lack of data on their ability to predict treatment response.

Identifying the efficacy and crucial prognostic predictors governing the success of biological therapy stands as a significant unmet need in modern personalized medicine.
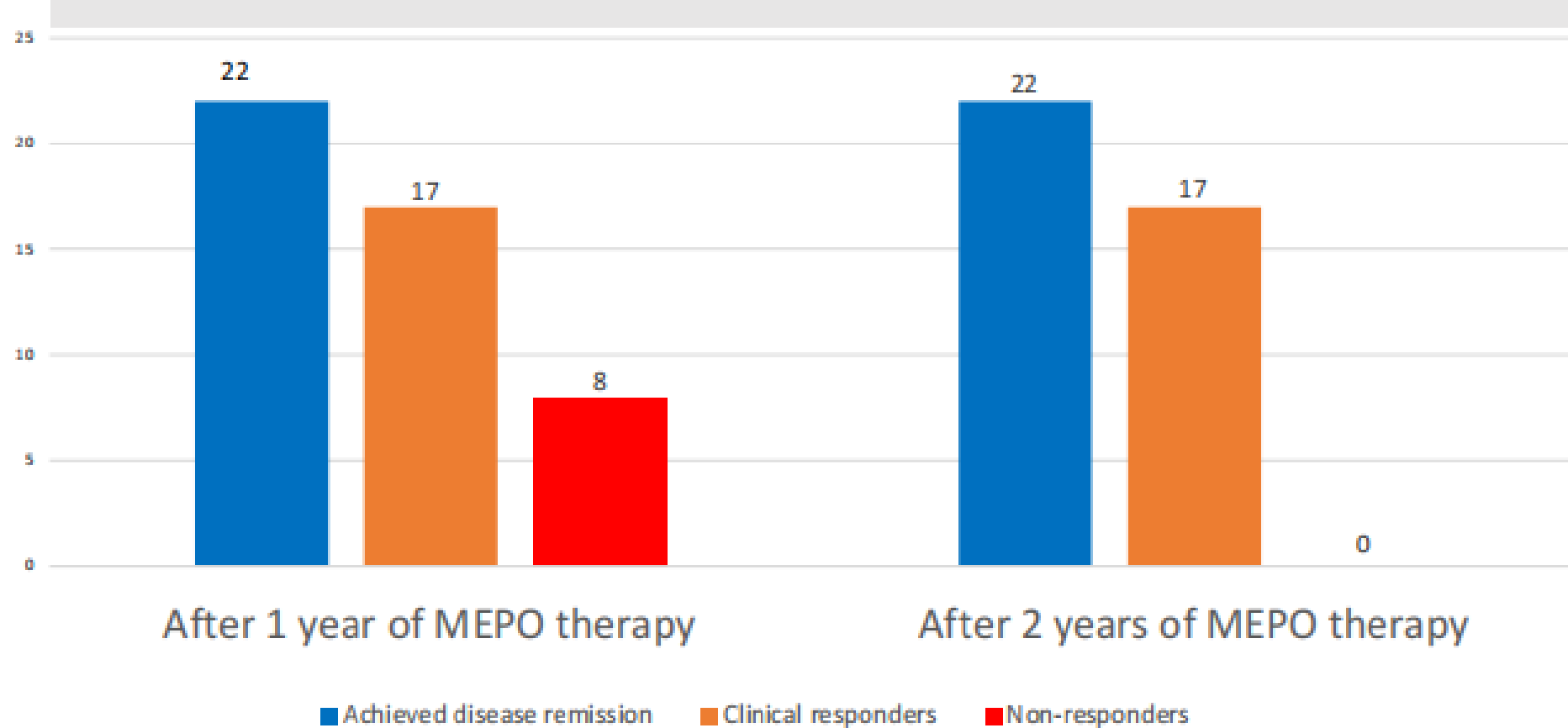
Results

1. Retrospective analysis of disease remission in patients with severe asthma treated with mepolizumab and its duration after treatment discontinuation.
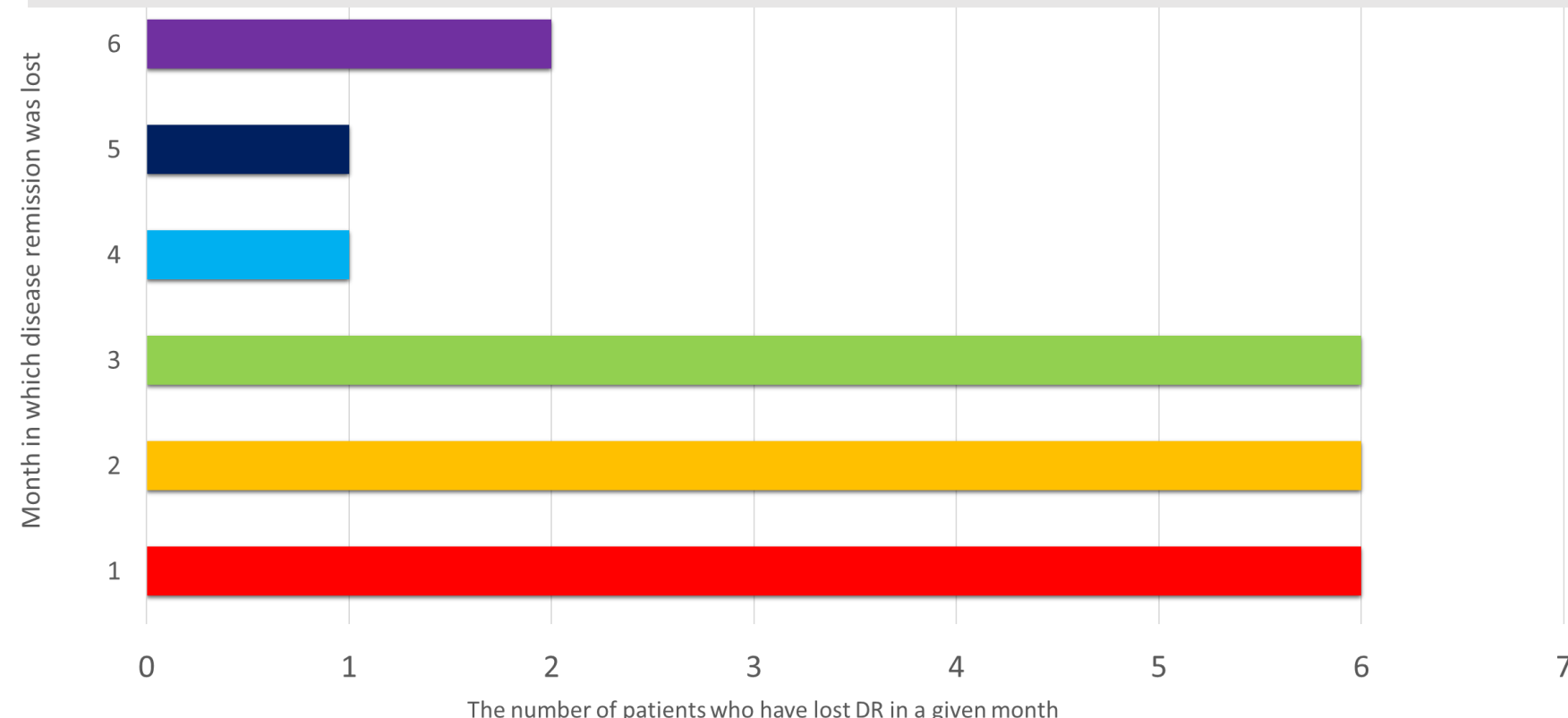
Efficacy assessment after one year of MEPO treatment n=74, (%)

Less restrictive criteria (ACQ < 1,5): Achieved disease remission 42, Clinical responders 43, Non-responders 15
More restrictive criteria (ACQ <0,75): Achieved disease remission 18, Clinical responders 67, Non-responders 15

■ Achieved disease remission ■ Clinical responders ■ Non-responders

Efficacy assessment after one year and two years of MEPO treatment (n) N= 47

After 1 year of MEPO therapy: Achieved disease remission 22, Clinical responders 17, Non-responders 8
After 2 years of MEPO therapy: Achieved disease remission 22, Clinical responders 17, Non-responders 0

■ Achieved disease remission ■ Clinical responders ■ Non-responders

The number of patients who lost DR in the months following discontinuation of mepolizumab therapy.

Month in which disease remission was lost
The number of patients who have lost DR in a given month

2. Retrospective analysis of disease remission in patients with severe asthma after one year on benralizumab therapy.

Definition of disease remission

- EOS <300 cells/μL
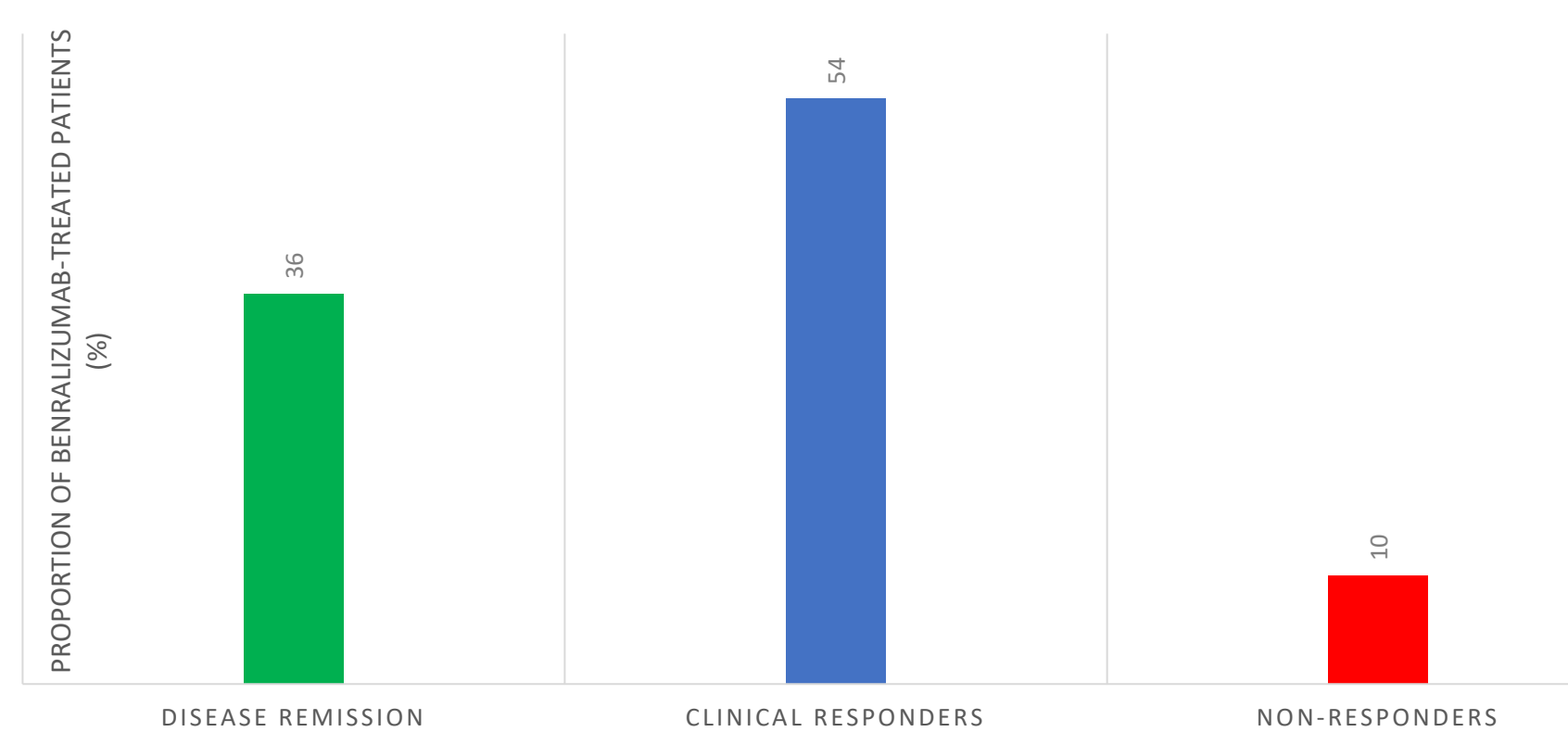- No need for oral corticosteroids
- Zero exacerbations requiring OCS and hospitalizations
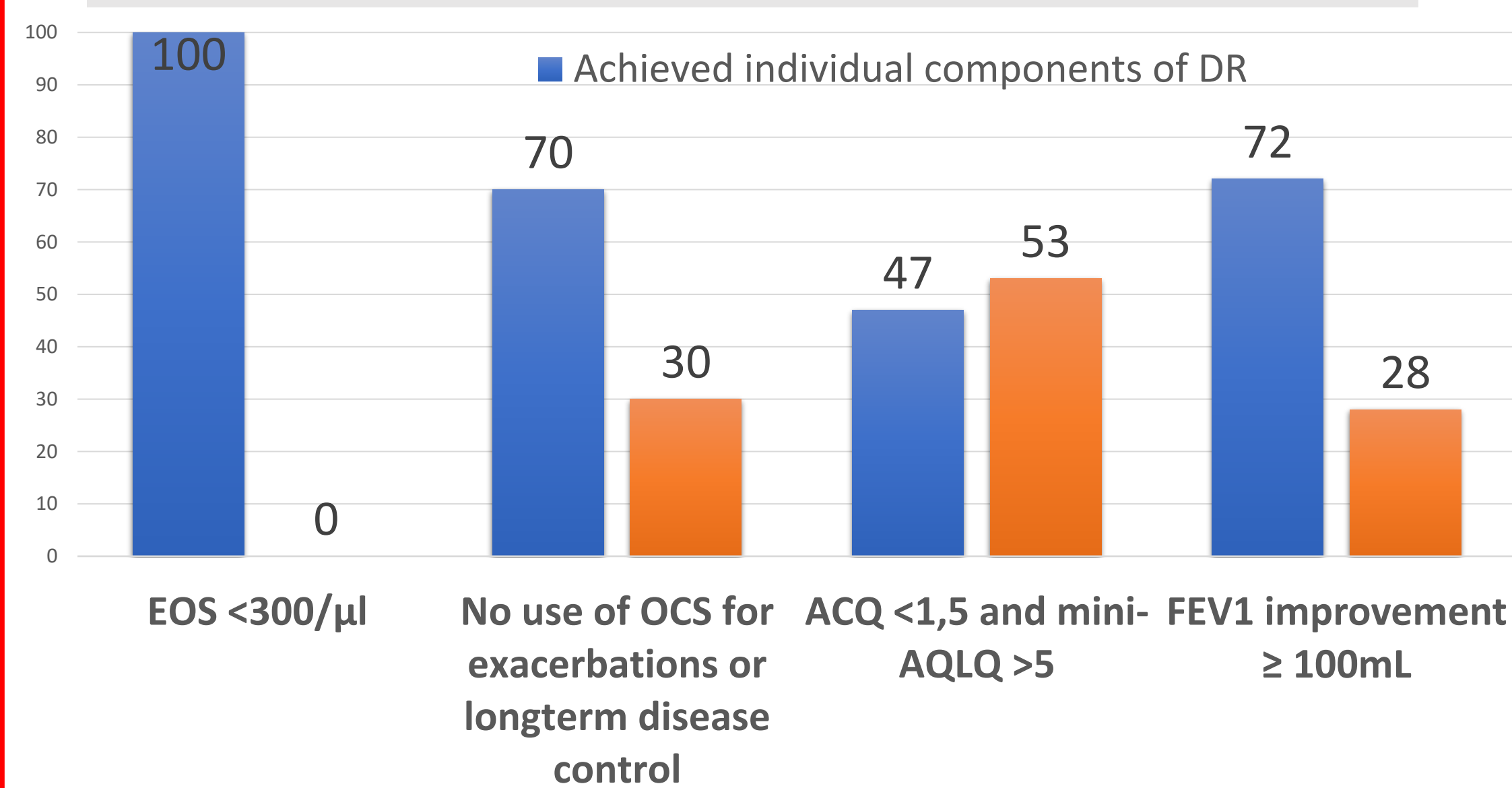- ACQ <1,5
- FEV1 improvement ≥100 mL.

Disease remission in severe asthma patients after 1 year of benralizumab treatment (n=103)

PROPORTION OF BENRALIZUMAB-TREATED PATIENTS (%)

DISEASE REMISSION 36, CLINICAL RESPONDERS 54, NON-RESPONDERS 10

The proportion of patients meeting the individual components of disease remission after one year of BENRA therapy (%)

■ Achieved individual components of DR

EOS <300/μl: 100, 0
No use of OCS for exacerbations or longterm disease control: 70, 30
ACQ <1,5 and mini-AQLQ >5: 47, 53
FEV1 improvement ≥ 100mL: 72, 28

3TR-ABC ASTHMA BIOLOGICS COHORT

Baseline (week 0)

Standard examination package:

- Informed consent
- Demographics
- Medication status
- PROs
- Lung function
- FeNO
- Blood
- Urine

+24 week

Standard examination package:

- Informed consent
- Demographics
- Medication status
- PROs
- Lung function
- FeNO
- Blood
- Urine

The planned study group – 50 people qualified for biological treatment with mepolizumab, and benralizumab. The collection of research material will take 2.5 years, another year is envisaged for the preparation of results and writing publications.

Conclusion

The presented analysis indicates the high effectiveness of MEPO and BENRA in achieving diseace remission.

There are large differences in the number of patients achieving clinical remission depending on the choice of cut-off point in asthma control questionnaires, which requires further analysis on this issue