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BACKGROUND

- Self-injectable biologic therapies can be dose-escalated to treat patients with inflammatory bowel disease (IBD) who experience a loss of response to Food and Drug Administration-approved dosing.^{1,2,3}
- Studies evaluating clinical characteristics and short-term outcomes in this population are limited.

OBJECTIVES

To assess clinical characteristics and 3-month outcomes for patients prescribed alternate-dose therapy.

METHODS

DESIGN Single-center retrospective cohort analysis

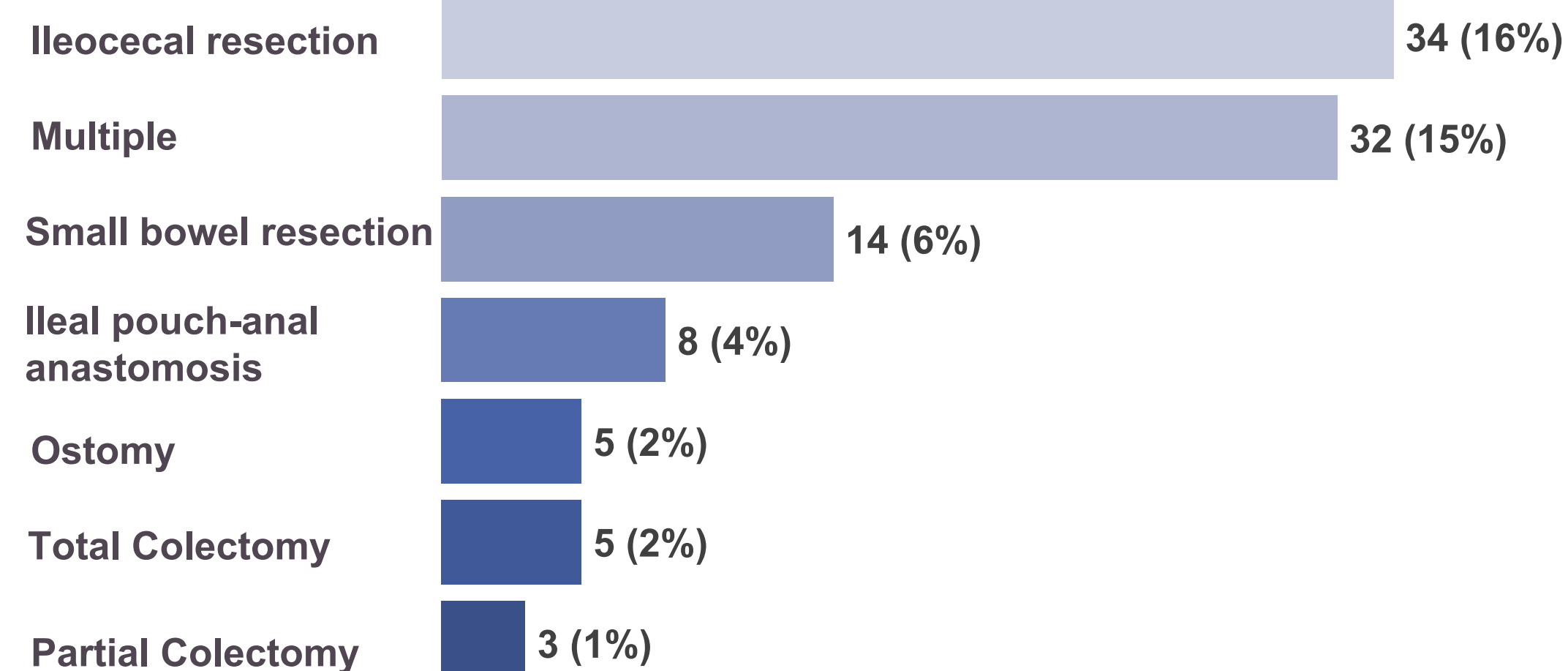
INCLUSION Adult patients prescribed alternate-dose ustekinumab, adalimumab, golimumab or certolizumab from January – December 2018

EXCLUSION Insurance approval not completed by center's specialty pharmacy
Medication fulfilled through manufacturer or medical benefit

DATA Baseline characteristics were assessed at time of prior authorization
Outcomes were assessed three months following prior authorization request

RESULTS

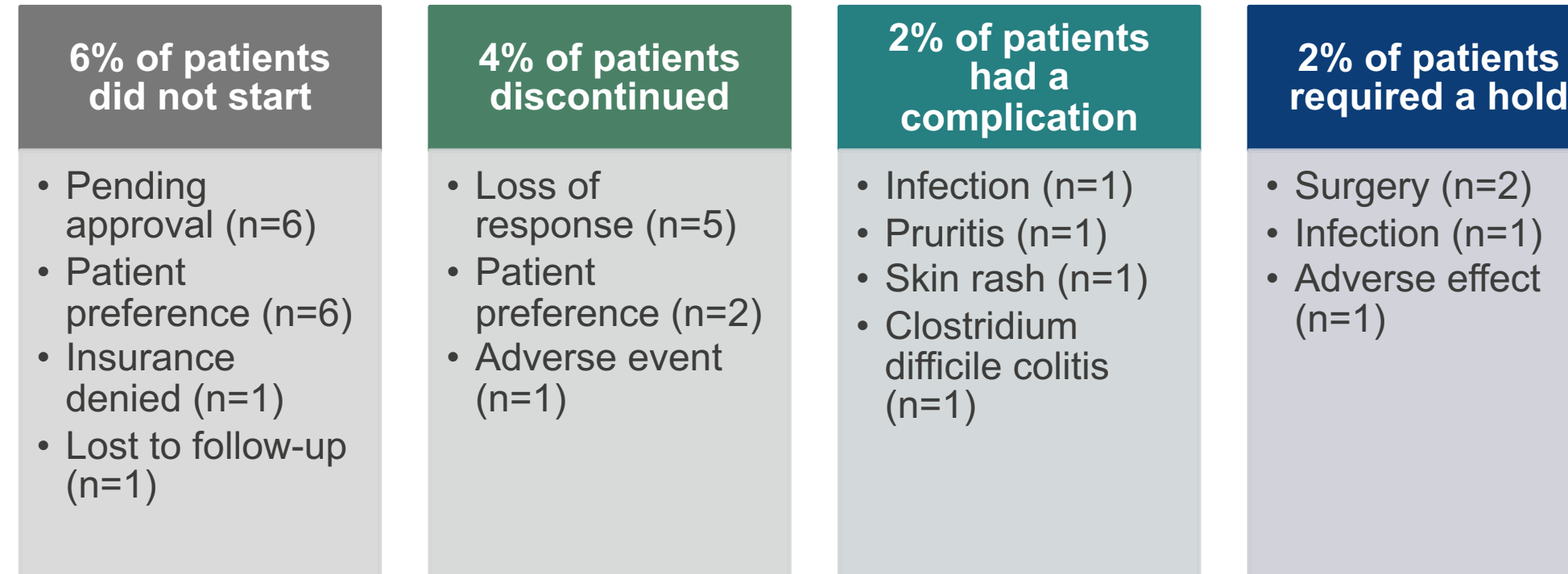
Figure 1. IBD-related surgical history (n=101)



46% of patients (n=101) previously underwent surgery, indicating moderate-to-severe disease.

15% of patients (n=32) had multiple previous surgeries, suggesting more severe disease.

Figure 2. Alternate-dose treatment barriers

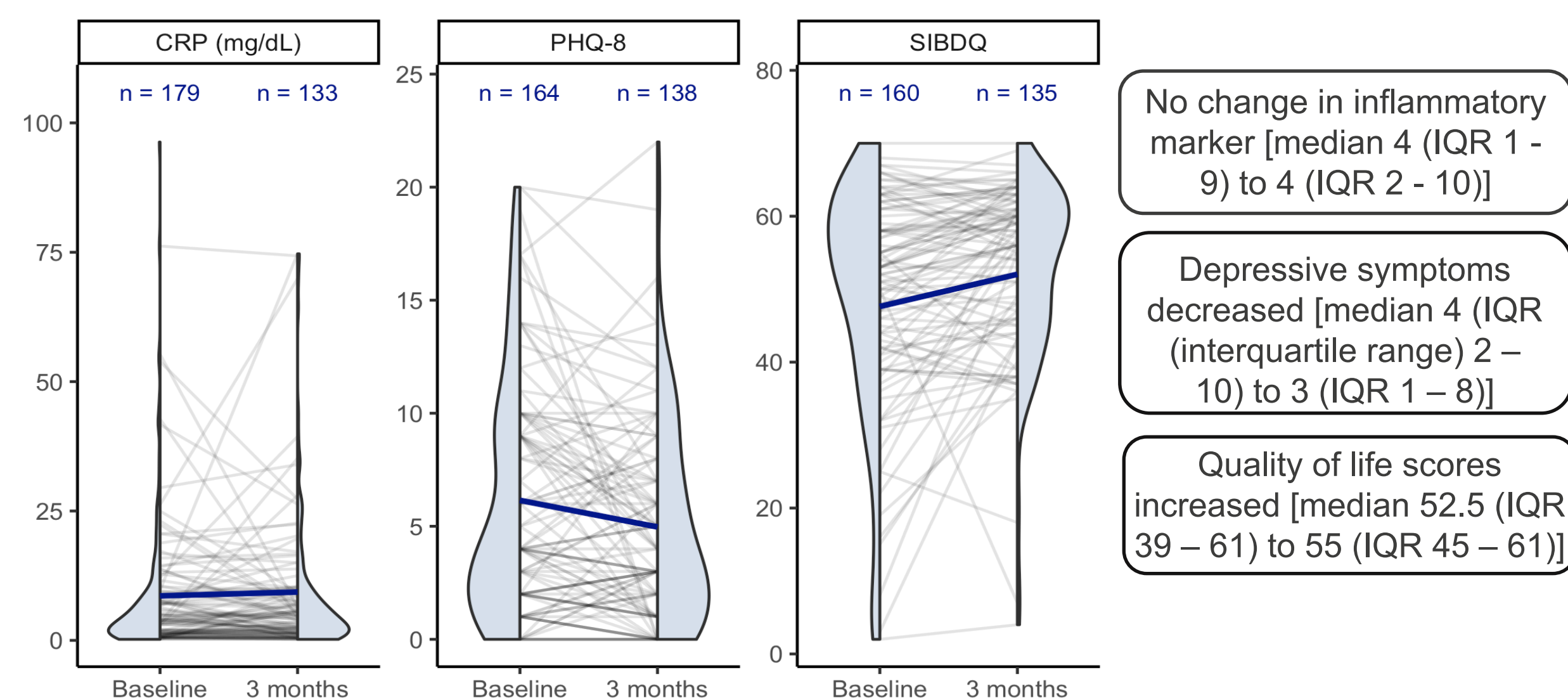


RESULTS

Table 1. Sample characteristics (n=220)

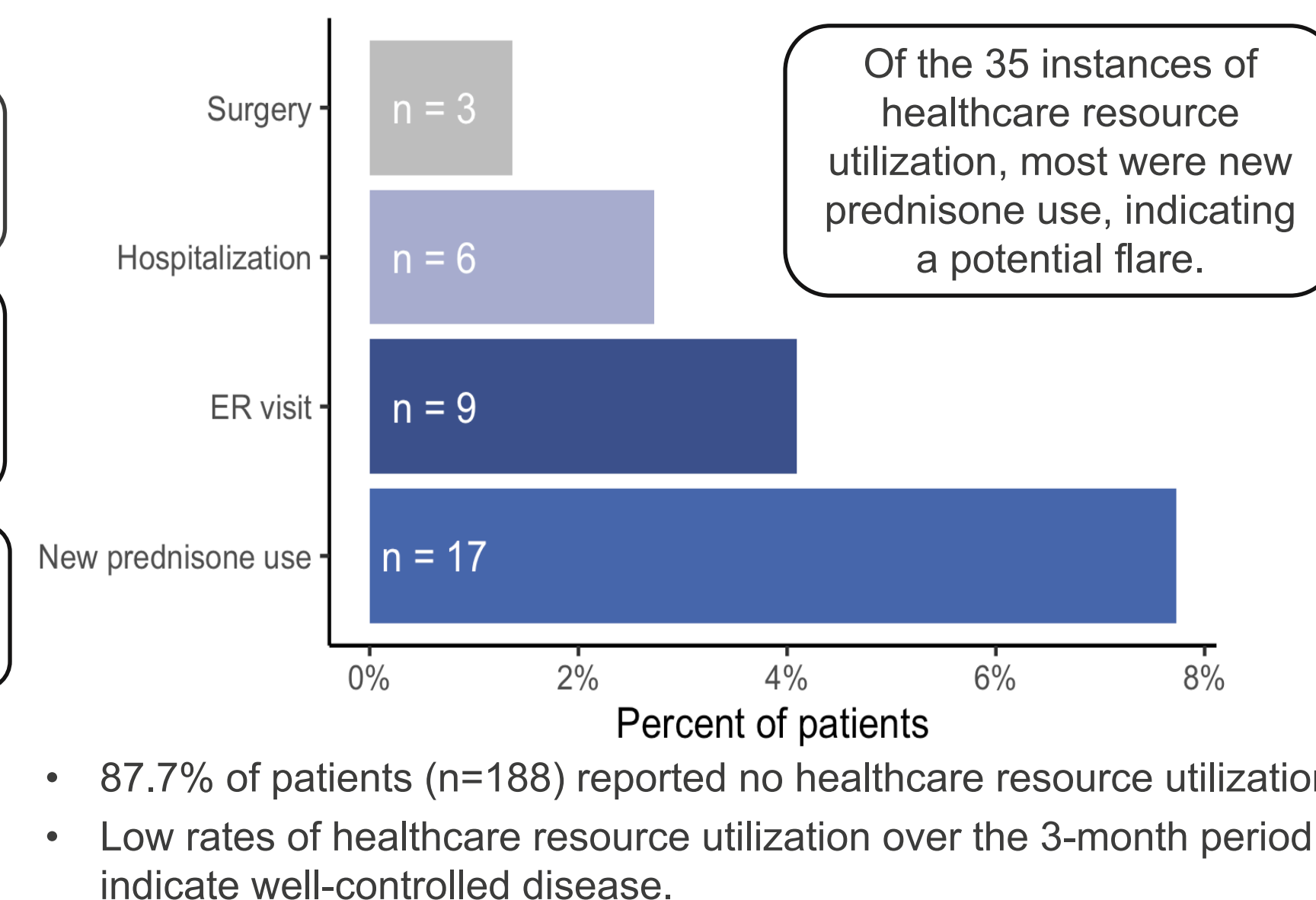
Characteristic	n (%)
Age, years, mean ± standard deviation	41 ± 14
Gender, female	116 (53)
Race	
Caucasian	210 (96)
African American	8 (4)
Asian Indian	1 (<1)
American Indian/Alaskan Native	1 (<1)
Smoking status	
Nonsmoker	146 (66)
Previous smoker	52 (24)
Current smoker	22 (10)
Previous IBD-related surgery, yes	101 (46)
Psychiatric diagnosis	
Depression	67 (31)
Bipolar disorder	45 (21)
Anxiety	6 (3)
Biologic therapy	
ustekinumab	132 (60)
adalimumab	84 (38)
golimumab	3 (1)
certolizumab	1 (<1)

Figure 3. Change in CRP, PHQ-8 and SIBDQ from baseline to three months



CRP: C-reactive protein; PHQ-8: Patient Health Questionnaire-8; SIBDQ: Short Inflammatory Bowel Disease Questionnaire

Figure 4. Healthcare resource utilization over three months



CONCLUSIONS

- Patients requiring alternative-dose biologic therapy typically have a long and complex disease history and have received standard-dose therapy for more than one year.
- We observed improvement in patient-reported symptoms in SIBDQ, and PHQ-8 scoring within a 3-month interval. Further research to evaluate the long-term outcomes is needed.