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# Elderly patients treated with afatinib in clinical practice – results from the prospective non-interventional study GIDEON

#125P

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## Introduction

- Afatinib, an irreversible ErbB family blocker, is approved for the first-line treatment of patients with locally advanced or metastatic NSCLC with activating *EGFR* mutation(s)[1]
- Numerous randomised clinical trials have shown significantly improved efficacy outcomes with afatinib compared with chemotherapy or the first-generation EGFR tyrosine kinase inhibitor, gefitinib, and a manageable safety profile[2–5]
- The prospective, non-interventional study (NIS), GIDEON, was undertaken to investigate the effectiveness and tolerability of first-line afatinib treatment when used in routine clinical practice in Germany[6]
- Elderly patients are often under-represented in clinical trials, which can lead to uncertainties regarding optimal treatment of such patients in routine clinical practice
- The GIDEON NIS enrolled a high proportion of patients aged ≥70 years, providing an opportunity to study the real-world use of afatinib in older individuals[6]
- Here, we report the results from a post-hoc analysis of elderly patients in the first interim analysis of the GIDEON NIS

## The GIDEON study[6]

- One hundred and sixty patients with confirmed *EGFR* mutation-positive NSCLC were recruited at 49 centres across Germany, between April 2014 and December 2016

| | |
|---|---|
| Primary endpoint | • PFS at 12 months |
| Key secondary endpoints | • PFS<br>• OS<br>• ORR (CR+PR)<br>• DCR (CR+PR+SD) |

- Interim findings among the entire treated population (N=151) included:
  - 12-month PFS: 54.6%
  - Median PFS: 12.9 months
  - Median OS (preliminary): >33 months
  - ORR: 73%
  - DCR: 90%

CR, complete response; DCR, disease control rate; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; SD, stable disease

## Methods

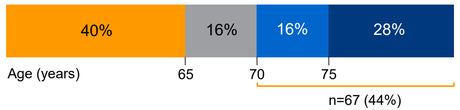
- This post-hoc analysis of the GIDEON study was conducted to investigate the efficacy and safety of afatinib in patients aged ≥70 years, when administered according to the approved label[1]
- All comparisons were descriptive

## Results

### Patient demographics and baseline characteristics

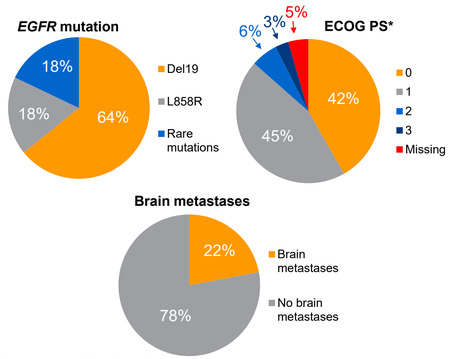
- Among the 151 patients treated in the GIDEON study, median age was 67 years (range 38–89)
- In total, 67 patients (44%) were aged ≥70 years (**Figure 1**)

**Figure 1. Age distribution in the overall GIDEON population (N=151)**




- Key patient baseline characteristics are shown in **Figure 2**

**Figure 2. Key baseline characteristics among patients aged ≥70 years (n=67)**




*Percentages do not total 100 due to rounding
ECOG PS, Eastern Cooperative Oncology Group performance score

## Results (cont'd)

### Afatinib starting dose and dose modifications

- There was a trend towards lower starting dose in patients aged ≥70 years, compared with those aged <70 years (**Figure 3**)
- The percentage of patients requiring dose reductions appeared similar between patients aged <70 years and ≥70 years (**Figure 4**)

**Figure 3. Starting dose of afatinib among patients aged <70 years and ≥70 years**

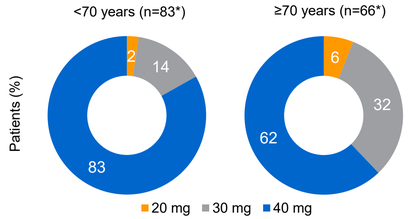
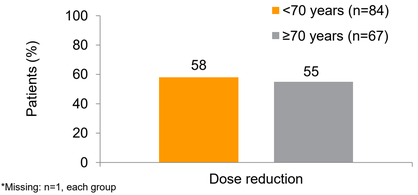



**Figure 4. Afatinib dose reductions among patients aged <70 years and ≥70 years**




*Missing: n=1, each group

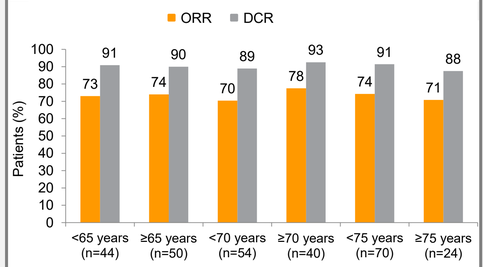
## Efficacy

### Response and survival

- Elderly patients had similar ORR and DCR compared to younger patients (**Figure 5**)
- In patients aged ≥70 years:
  - ORR was 78%
  - DCR was 93%
- 12-month PFS rate in patients aged ≥70 years was 62% (**Figure 6; Table 1**)

## Efficacy (cont'd)

**Figure 5. ORR and DCR in different age groups**

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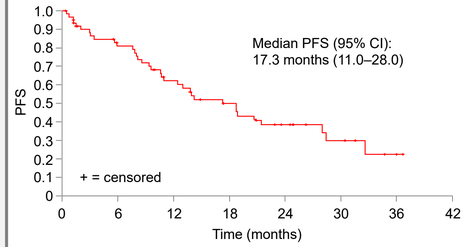



**Table 1. 12-month PFS rate**

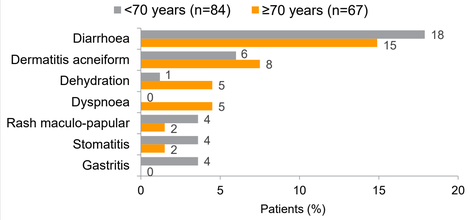
| Patient subgroup* | 12-month PFS rate (95% CI) |
|---|---|
| Age <70 years (n=80) | 49.1% (37.3–59.8) |
| Age ≥70 years (n=62) | 62.2% (48.0–73.6) |
| All patients (n=142) | 54.6% (45.6–62.8) |

*Nine patients were not evaluable
CI, confidence interval

## Safety

- Treatment-emergent adverse events (TEAEs) in the GIDEON study were consistent with the known safety profile of afatinib, identified in the LUX-Lung 3, 6, and 7 clinical trials[2–4]
- Afatinib-related grade ≥3 TEAEs were similar in patients aged ≥70 years and <70 years, with diarrhoea being the most common (**Figure 7**)
- Eight patients aged ≥70 years (12%) and six patients aged <70 years (7%) discontinued due to serious adverse drug reactions

**Figure 7. Afatinib-related grade ≥3 TEAEs occurring in at least 3 patients in any subgroup**




## Key findings and conclusions

- Data from the GIDEON NIS provide important information on the routine clinical use of afatinib in elderly patients
- As 44% of the GIDEON population were aged ≥70 years, elderly patients were well represented in this study
- With an ORR of 78% and 12-month PFS rate of 62%, these data support the use of afatinib in elderly patients
- Further, the safety profile of afatinib in elderly patients was comparable to that seen in the younger subgroup

## References

1. European Medicines Agency. Giotrif® (afatinib). Summary of Product Characteristics. May 2018
2. Sequist LV, et al. J Clin Oncol 2013;31:3327–34
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https://tinyurl.com/y5n6re6w



Presented at the European Lung Cancer Congress (ELCC), Geneva, Switzerland, 10–13 April 2019

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*Corresponding author email address: Wolfgang.Brueckl@klinikum-nuernberg.de

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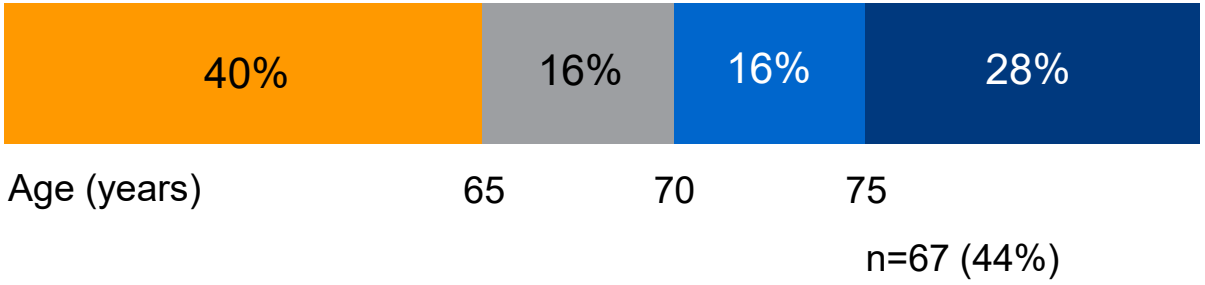


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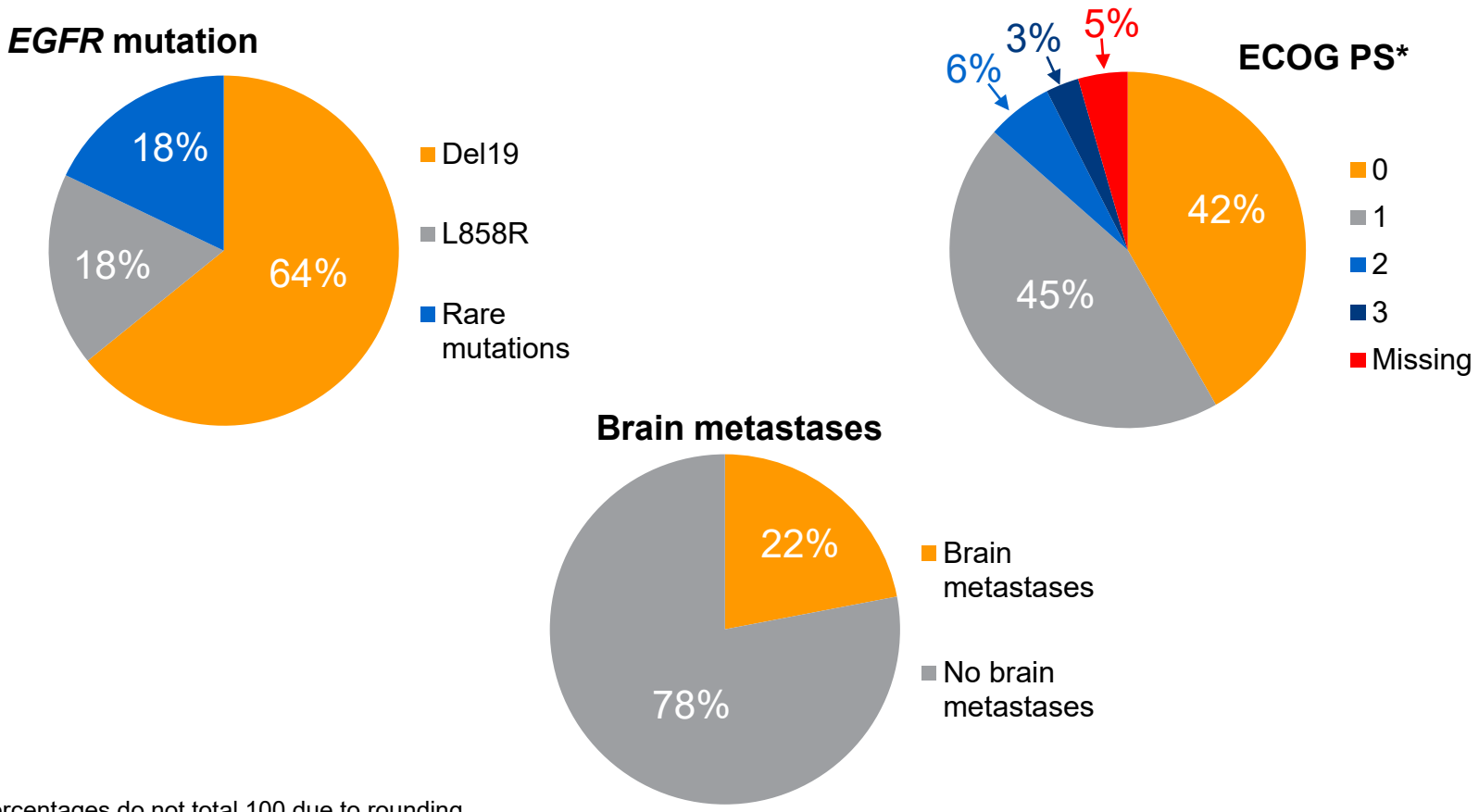


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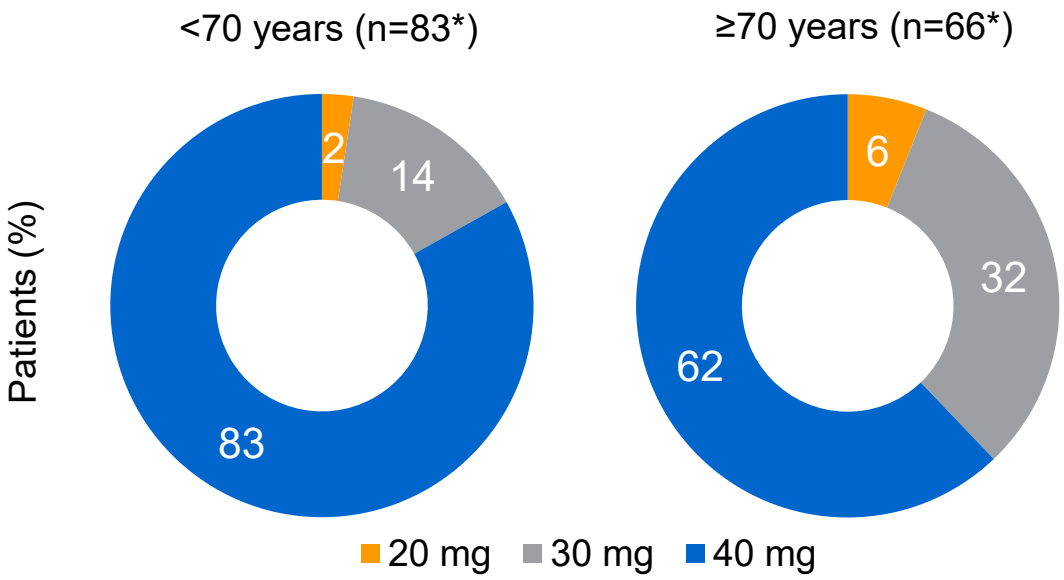


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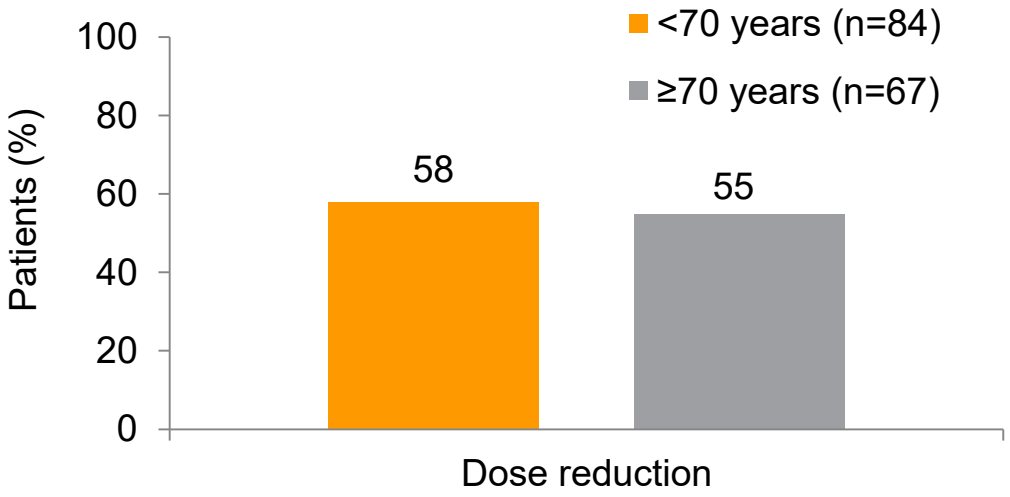

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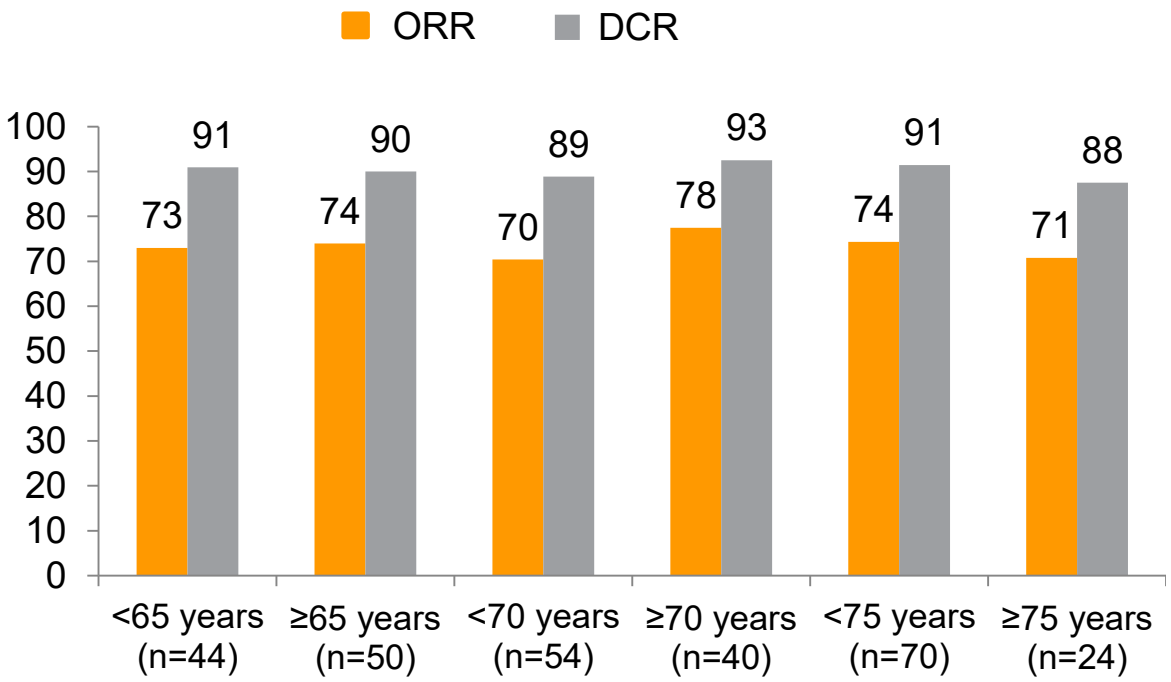


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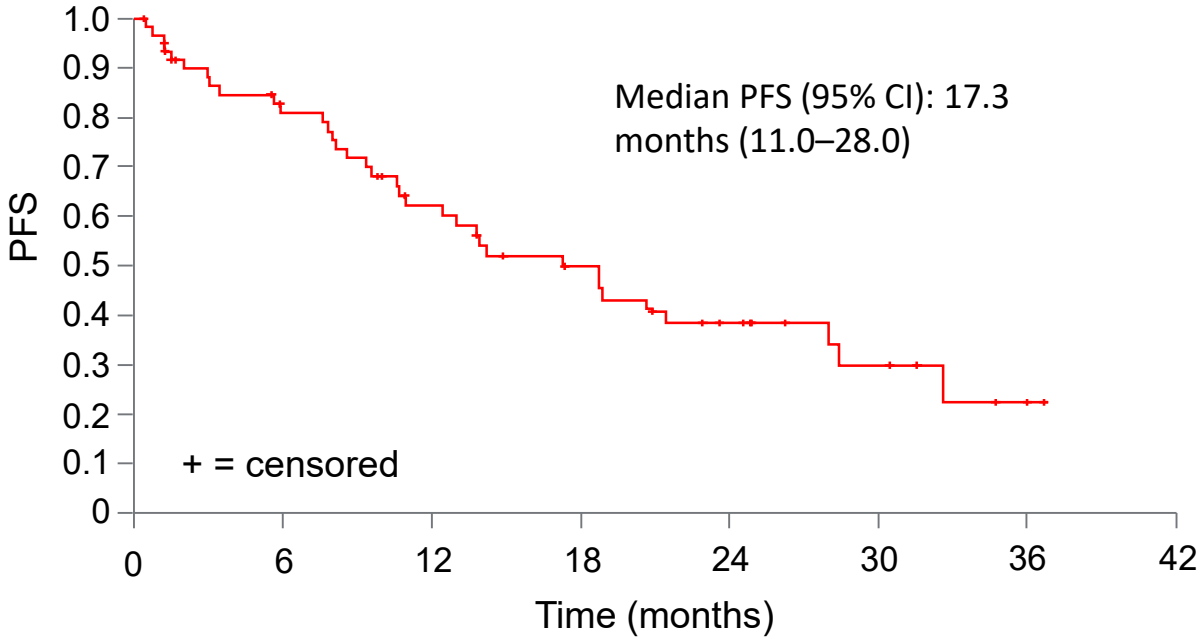

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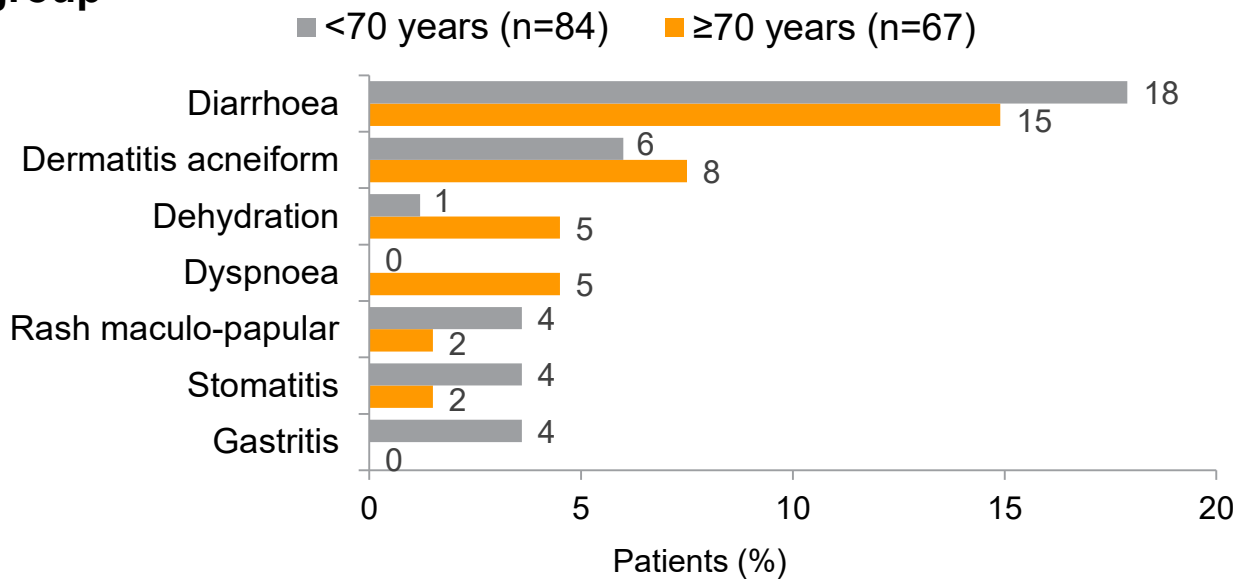

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