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## Background

- Perianal fistulas (PAF) are one of the most debilitating complications in Crohn's disease (CD)<sup>1</sup>
- PAF may impair overall quality of life (QoL) including social, sexual, and everyday activities<sup>2</sup>
- Despite the clinical relevance, few studies have addressed the patient perspective on the impact of PAF and complex PAF in CD on QoL
- Patient experience is important in treatment decision-making
- This study aimed to determine the impact of PAF and complex PAF in CD on patients' QoL in Europe

## Methods

- Data were collected using a self-selective, anonymous, cross-sectional survey that assessed the impact of PAF/complex PAF on QoL
- The questionnaire was developed by patient representatives and medical experts
- The survey addressed diagnosis, symptoms, and QoL, including close relationships, social life, sexual activity, and work life
- Complex PAF data were patient reported, based on their physician's diagnosis
- The survey was available in 11 languages and accessible on the European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA) website and national inflammatory bowel disease patient association websites from July 15 to December 31, 2019
- QoL was assessed using a 10-point scale (1, no impact; 10, high impact)

## Statistical analysis

- Categorical variables were expressed as percentages and continuous variables as mean ± standard deviation
- Data analysis was carried out using R version 4.0

## Results

### Demographic and disease characteristics

- Of the 820 respondents with CD (female, 67.2%; mean age, 40.8 years), 532 (64.9%) reported PAF, of whom 272 (51.1%) reported complex PAF (Table 1)
- Data from more than 10 countries/regions, including Italy, Spain, Portugal, Greece, among others, were recorded and analyzed in this study

Table 1. Demographic characteristics of survey respondents

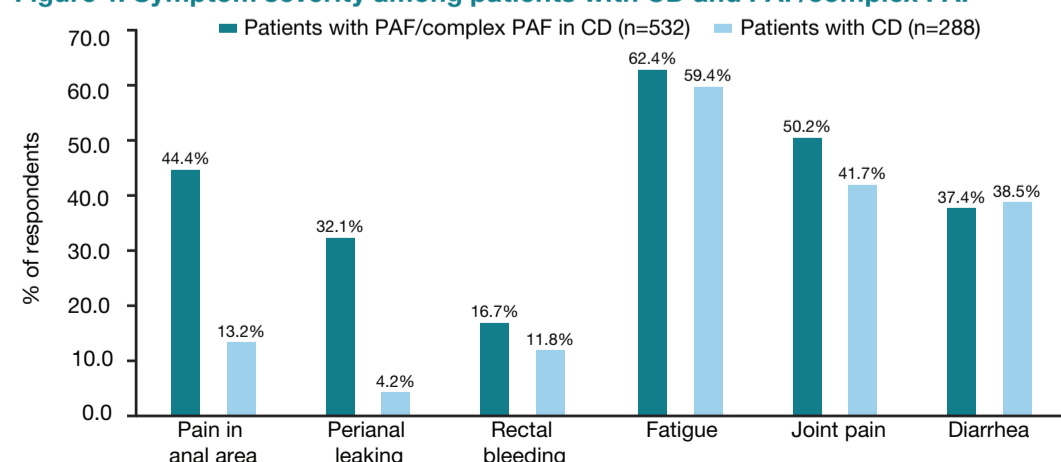
Characteristics, n (%)	Overall (N=820)
Age, years, mean (SD)	40.8 (11.9)
Female	551 (67.2%)
Crohn's disease status	
Active	311 (37.9%)
Non-active	492 (60.0%)
Crohn's disease duration, years	
<1	66 (8.0%)
1–5	177 (21.6%)
6–10	148 (18.0%)
11–15	110 (13.4%)
>15	319 (38.9%)
Presence of perianal fistula	532 (64.9%)
Presence of complex perianal fistula	272 (51.1%)

SD, standard deviation

### Symptom severity among patients with CD and PAF/complex PAF

- CD patients with PAF/complex PAF had experienced or were currently experiencing more anal pain and perianal leaking than those without PAF/complex PAF (Figure 1)

Figure 1. Symptom severity among patients with CD and PAF/complex PAF

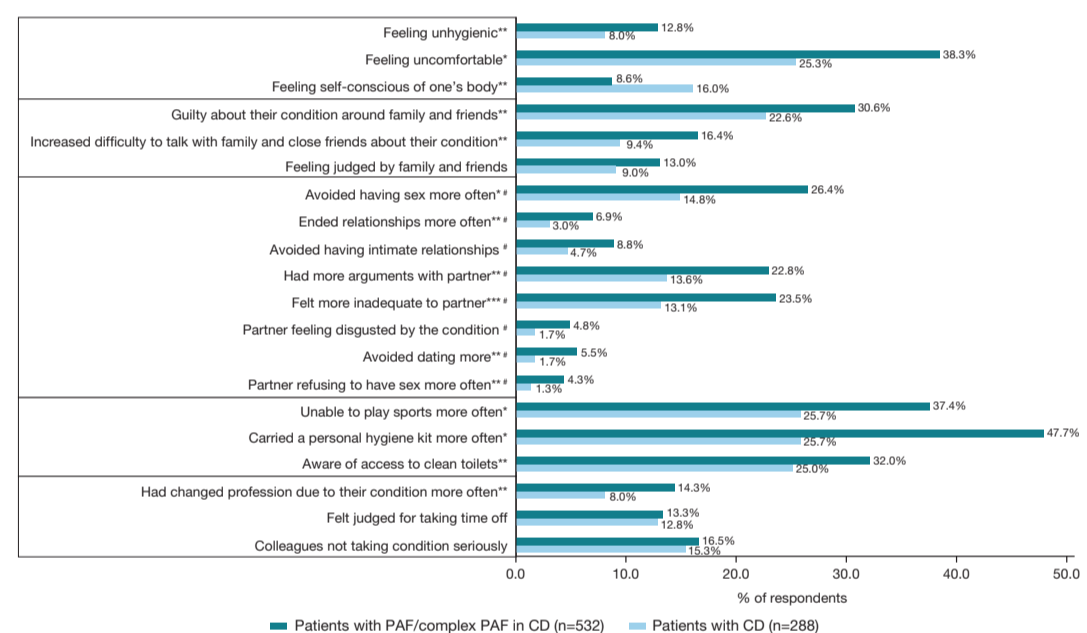


Number of respondents: 820; the graph includes proportion of patients who reported experiencing these symptoms currently  
CD, Crohn's disease; PAF, perianal fistula

### Impact of PAF/complex PAF in CD on patients' QoL and relationships

- Patients with CD and PAF/complex PAF reported a greater impact on overall QoL (6.91 vs. 6.18;  $p<0.001$ ), relationships with family and friends (5.54 vs. 4.78;  $p<0.001$ ), relationship with partner (5.24 vs. 4.11;  $p<0.001$ ), impact on social life (5.65 vs. 4.97;  $p=0.001$ ), and work life (5.54 vs. 5.12;  $p=0.02$ ) than patients with CD without PAF/complex PAF
- Overall, patients with PAF/complex PAF reported feeling more unhygienic, uncomfortable, and guilty about their condition toward family and friends than those without PAF/complex PAF
- Patients found it more difficult to talk with family and close friends about their condition
- Patients avoided having sex, ended relationships, had arguments with their partner, felt inadequate to their partner, avoided dating, and had their partner refuse having sex more often than those without PAF/complex PAF
- They were also unable to play sports (37.4% vs. 25.7%,  $p<0.001$ ), carried a personal hygiene kit (47.7% vs. 25.7%,  $p<0.001$ ), were aware of access to clean toilets (32.0% vs. 25.0%,  $p=0.04$ ), and had changed their profession/career due to their condition more often (14.3% vs. 8.0%,  $p=0.008$ ) than those without PAF/complex PAF (Figure 2)
- Women reported a significantly greater impact of PAF/complex PAF compared with men on the following parameters:
  - overall QoL (women: 6.93 vs. men: 6.09;  $p<0.001$ )
  - relationship with friends and family (5.54 vs. 4.73;  $p<0.001$ )
  - relationship with their partner (5.22 vs. 4.06;  $p<0.001$ )
  - social life (5.93 vs. 5.09;  $p=0.002$ )
  - work life (5.64 vs. 4.89;  $p<0.001$ )

Figure 2. Impact of PAF/complex PAF among patients with CD on QoL, relationships, social life, and work life



\* $p<0.001$ , \*\* $p<0.05$ , \*\*\* $p=0.001$ ; #The n values for relationship with partner are based on the presence of partner with fistula (n=421) or absence (n=236); this figure does not include all items from the survey  
CD, Crohn's disease; PAF, perianal fistula; QoL, quality of life

### Limitations

- Potential for selection bias due to the self-selective nature of the survey and being available online only in a limited number of languages
- Recall bias may also have affected some responses due to the retrospective nature of a few questions (for instance, questions on symptom severity at all times)

## Conclusions

- From the patients' perspective, PAF/complex PAF severely impact their overall QoL, sexual relationships, social life, and work life
- The results are suggestive of an impact of PAF/complex PAF on patients in addition to the existing impact of CD
- These results are important to consider when tailoring treatment strategy and patient services in a multidisciplinary approach to address individual patient needs

### References

- Marzo M et al. *World J Gastroenterol* 2015;21(5):1394-1403.
- Rencz F et al. *Eur J Health Econ* 2019;20(suppl 1):91-100.

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### Disclaimer

This poster is intended for healthcare providers and patient organizations only.