BURDEN OF COMPLEX PERIANAL FISTULAE IN PATIENTS WITH CROHN'S DISEASE IN PORTUGAL

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PRESENTED AT:

Virtual ISPOR Europe 2020 | 16-19 November

BACKGROUND AND OBJECTIVES

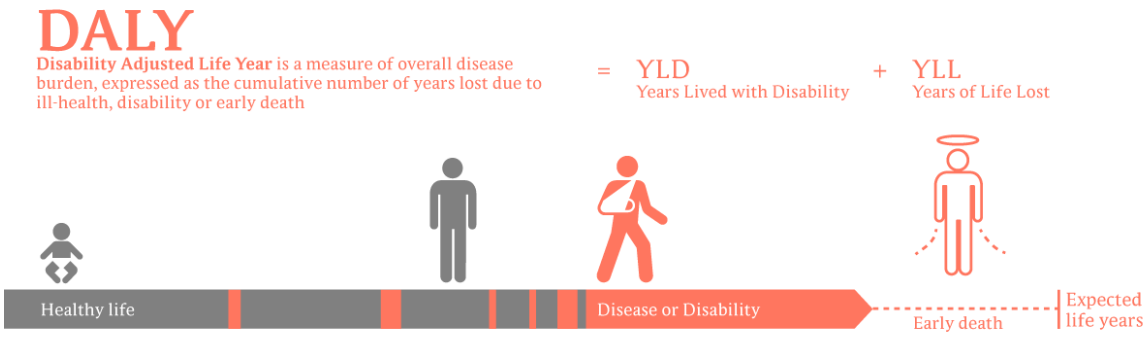
- Crohn's disease (CD) is a chronic inflammatory disease that might lead to complications such as fistulae. Complex perianal fistulae (CPF) are those involving the upper part of the sphincter complex, have multiple external openings (tracts) and are associated with pain. Generally treated with best supportive care options, the probability of cure is low and recurrence is frequent. CPF can result in high disease burden, diminishing health-related quality of life.[1]

- The objective of this study was to estimate the burden of CPF in adult patients with CD in Portugal mainland during 2017, using disability adjusted life years (DALY).

METHODS

- The burden of disease was measured in DALY, generally estimated as the sum of Years Lost due to Disability (YLD) and Years of Life Lost (YLL) due to premature mortality.[2]

Figure 1. DALY diagram.



DALY Disability adjusted life year (https://upload.wikimedia.org/wikipedia/commons/b/b5/DALY_disability_affected_life_year_infographic.png)by Planemad, licensed under CC BY-SA 3.0

Table 1. Disability weights per health state.

	Disability weight
Active fistulae	0,52
Fistulae closure	0,18
Post successful surgery	0,37
Post unsuccessful surgery	0,50

- As no national epidemiological data of patients with CPF in CD is available, the burden of disease estimation follows a prevalence based approach.
- It was assumed that no deaths were due specifically to CPF in CD. Therefore only YLD were estimated using a methodology in stages.
- First, a pharmacoepidemiological approach was used to estimate the prevalence of inflammatory bowel disease patients treated with biological agents prescribed in gastroenterology (adalimumab, infliximab and vedolizumab), based on the latest national sales data. Continuous intake of these medicines according to its defined daily dose (WHO) was assumed. [3]
- Second, the proportions of Crohn's to ulcerative colitis (50.7% according to Azevedo *et al*.[4]) and, of those receiving anti-tumour necrosis factor treatment (28% - Göttgens *et al*.[5]) were used to estimate prevalent patients with CD. A compliance rate of 90% was assumed.
- Finally, prevalence rates of CPF in CD were based on Göttgens *et al*.[5], estimating an average annual incidence rate of primary CPF at 0.62%.
- Next a cumulative incidence model of CPF in CD patients was used to estimate the prevalence in each disease state: active fistula; fistula closure; post successful surgery; post unsuccessful surgery. This model was based on the health technology assessment of darvadstrocel n Portugal considering the outcomes of patients on Best Supportive Care arm in ADMIRE-CD trial.[6,7] A rate of 6.2% of CD patients were estimated to have an active CPF and 25,7% had a CPF once in their lifetime.

- Distribution of prevalence rates per age group and sex was based on Azevedo *et al*.[4], based on national mainland population.[8]
- Disability weights per health state were based on utility values from cost-utility studies.[9-11]
- Based on portuguese clinical experts, 70% of patients with CPF have active luminal CD and 5% of patients in CPF remission have active luminal CD.

RESULTS

- In 2017, 3,800 CD patients had been previously diagnosed with CPF and 741 CD patients had active CPF.
- With DALY solely based on YLD, the overall burden was estimated at 996 DALY, of which 382 DALY were due to the active phase of the disease.
- The average burden per patient was estimated at 0.08 DALY per CD patient and at 0.52 DALY per patient with an active CPF in CD.

Figure 2. DALY attributable to CPF in CD patients, Portugal mainland, 2017.

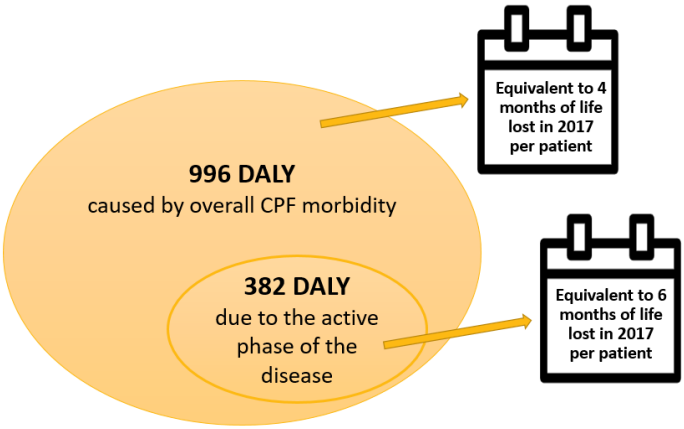
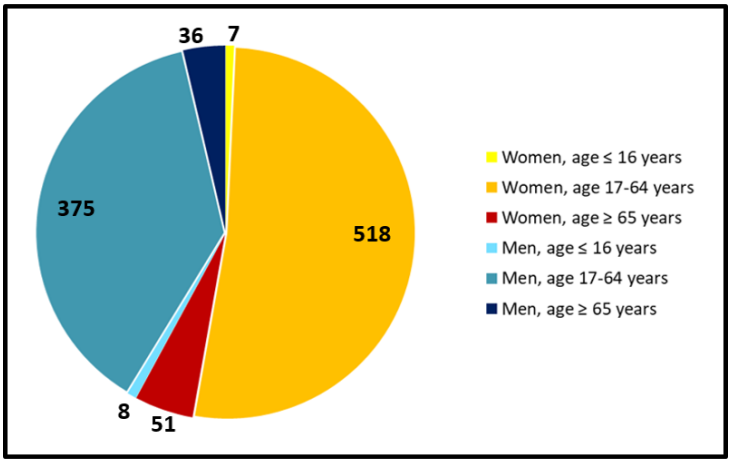


Figure 3. DALY attributable to CPF in CD patients: sex and age-group distribution.



- The major limitation of this study was the lack of national epidemiological data of patients with CPF in CD. Yet, this is the first study to assess the burden of CPF in CD in Portugal.

CONCLUSIONS

- In 2017, CPF-CD was responsible for a burden of 996 DALY, of which 382 are due to the active phase of the disease. In the active phase of the disease, DALY are equivalent to 6 months of life lost per patient, in 2017.

- Despite the low prevalence of CPF in CD, the burden of disease per patient is high. This reflects the importance of the disease and justifies further attention from healthcare decision makers.

ACKNOWLEDGEMENTS

- This study was funded by Takeda Farmacêuticos Portugal, Lda. Funding was independent of the study outcomes.

- We acknowledge the clinical experts for its valuable inputs and validation of the model: Professor Fernando Magro, Dr. Luís Correia, Dr. Francisco Portela and Drª. Paula Lago.

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