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### CROHN'S DISEASE: AN ECONOMIC ASSESSMENT OF BIOLOGICAL DRUGS IN ITALY

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#### BACKGROUND

Crohn's disease (CD) is a chronic, progressive and disabling inflammatory bowel disease (IBD) that can affect the entire gastrointestinal tract. The use of steroids and immunomodulators (such as azathioprine and methotrexate) has not decreased the need for surgery, nor has decreased hospitalization rates either. The introduction in 1998 of the so-called biological drugs, anti-tumor necrosis factor (TNF)-based, revolutionized both the treatment paradigms and the disease management, improving prognosis, but at the same time being characterized by higher costs and the need of hospitalizations for their administration. Beside a well-established biological drugs' efficacy, only few economic evaluations are present in published literature concerning the cost-effectiveness ratio of these drugs, some of which pointing out a wide uncertainty profile.

#### OBJECTIVES

The Workshop in Pharmacoeconomics (WEF) group, after two years dealing with the therapeutical area of hepatitis, applied its multidisciplinary and multistakeholder HTA-based method to IBDs (for further information see poster PHP159). The WEF-IBD study had a dual objective: 1) verify the improvements in quality of life (QoL) due to biological drugs administration to Crohn's disease patients and 2) evaluate their cost-effectiveness versus the standard steroid-based therapy.

#### METHODS

A survey was jointly prepared by clinicians and pharmacoeconomists and administered in 9 centers in different Regions of Italy. The questionnaire was set up to detect QoL through a Visual Analogue Scale (VAS) and EQ-5D and to assess patients' profile (age, gender, job) and clinical features (time-to-first diagnosis, current and at-diagnosis Montreal classification, current and at-diagnosis treatments, past surgical procedures, hospitalizations). Collected data were then used in a statistical regression model and an economic assessment complete of probabilistic sensitivity analysis was performed comparing costs and utilities of the considered treatments.

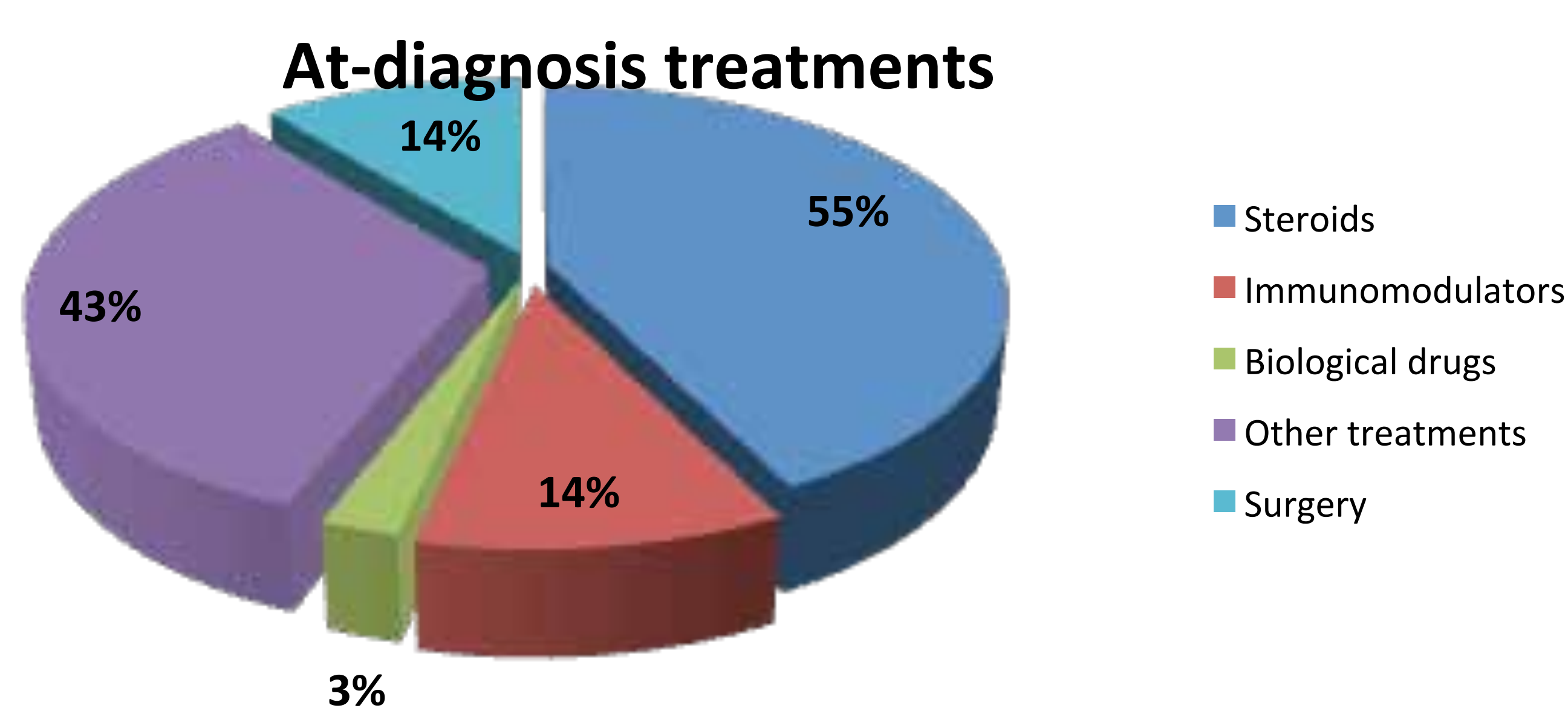
#### RESULTS

A total of 348 questionnaires were collected, giving back a population with a mean age of 42, 52% male, 58% actively working, 52% undergone surgical interventions, and 66% being already administered previous therapies. The mean number of outpatients visits was 4.15 per year, with 0.23 hospitalizations per year (Table 1).

N	348	
Mean age	42,09	
Gender	M	52%
	F	48%
Full health state	Yes	32%
Worker	Yes	58%
Other pathologies	Yes	39%
Steroids (diagnosis)	Yes	55%
Immunomodulators (diagnosis)	Yes	14%
Biological drugs (diagnosis)	Yes	3%
Other treatments	Yes	43%
Previous surgery	Yes	52%
Previous therapies	Yes	66%
Mean numbers of visits per year	4,149948	
Mean numbers of hospitalizations per year	0,229695	

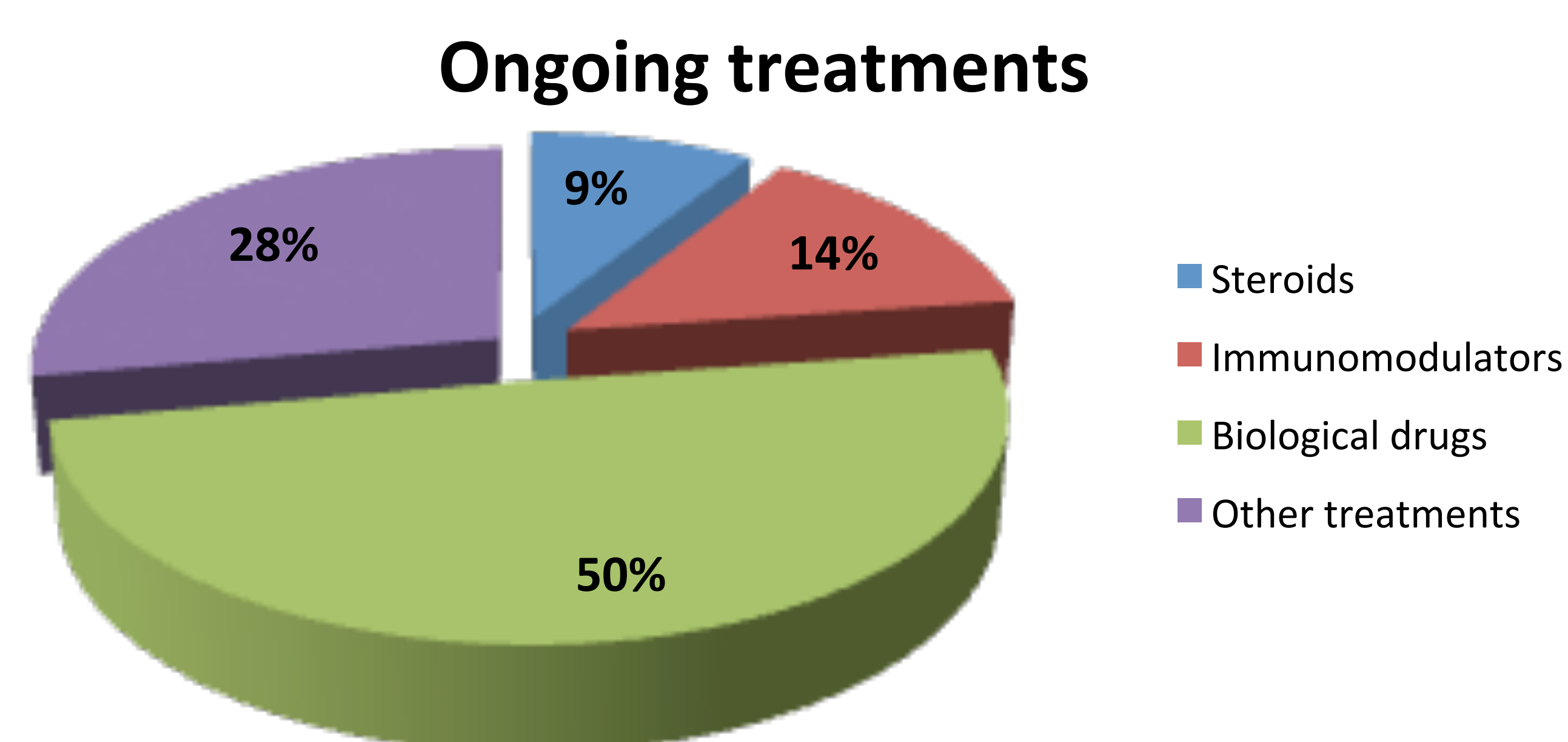
At diagnosis, the 55% of patients were treated with steroids, while only the 3% with biological drugs (Figure 1).

Figure 1



At the time of survey administration, the 9% of patients were treated with steroids, and the 50% with biological drugs (Figure 2).

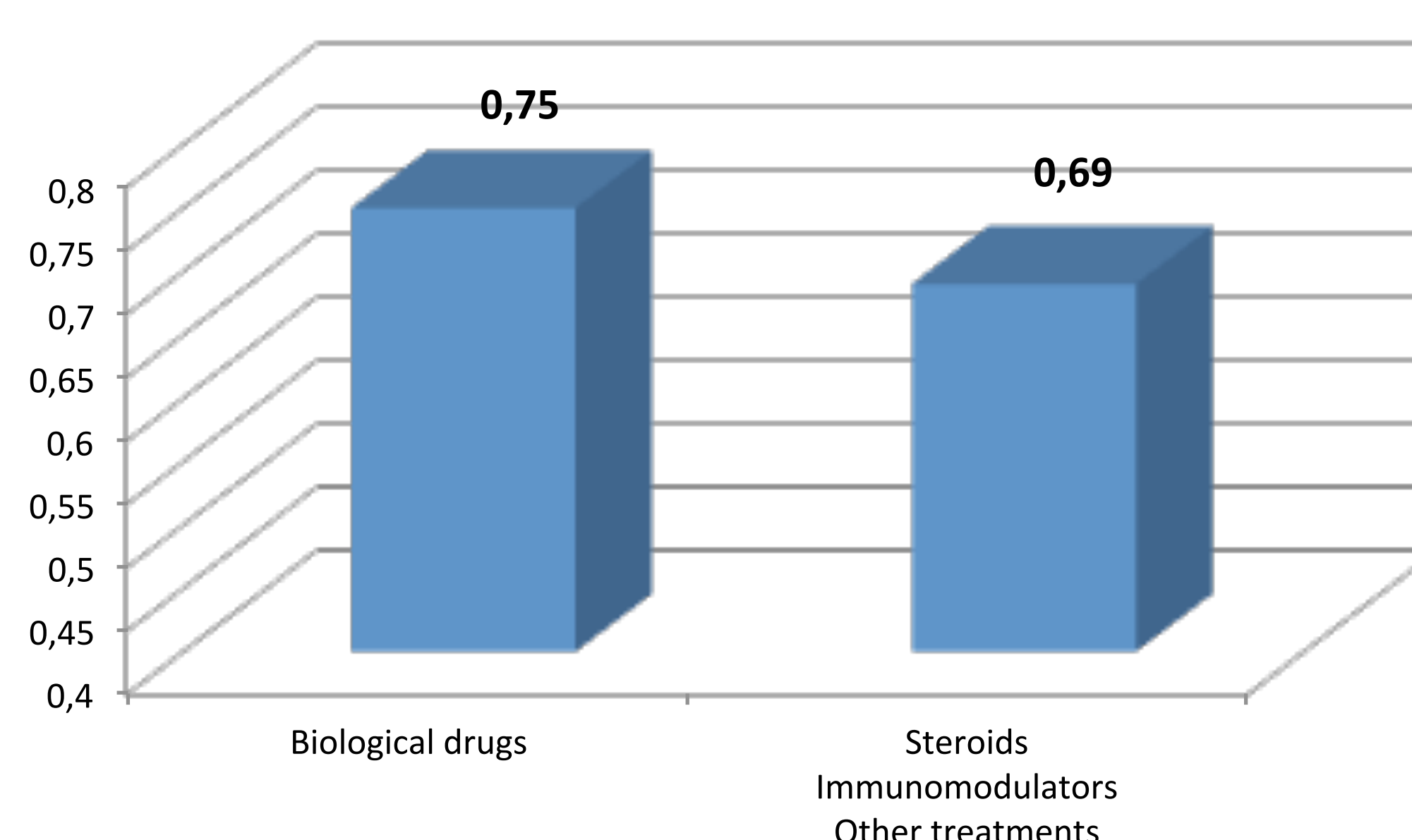
Figure 2



Concerning the QoL analysis, collected data showed that patients currently treated with biological drugs assign a higher score to their health state versus patients under other regimens (0.75 vs. 0.69, Figure 3).

Figure 3

#### Mean VAS score (ongoing treatment)



Data were then used to populate a statistical regression model in which the dependent variable was the QoL (EQ-5D dimensions), while the independent variable was represented by the therapy with biological drugs (controlled by subject variables such as age, gender, diagnosis, hospitalizations, outpatients visits).

Results showed that the use of biological drugs significantly improves:

- 1) pain-discomfort;
- 2) anxiety and depression.

Moreover, these results appear stronger in patients with comorbidities.

The model pointed out that results are statistically significant in patients staged from moderate to severe according to the Montreal classification of the disease.

According to the Italian NHS perspective, considering annual drug costs and the disease cost (outpatients visits, hospitalizations, diagnostic procedures), the economic assessment revealed biological drugs to be cost-effective only in more severe settings of patients (€ 26.000 – 38.000 /QALY), but not in mild and moderate Crohn's Disease (€ 58.000 - 328.000 /QALY).

#### CONCLUSIONS

The results of the analysis, based on simulation models and real practice data, are consistent with evidences from other Countries and thus biological drugs can be considered a good healthcare investment in severe cases of Crohn's Disease.



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