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**DIAGNOSTIC DELAY AND ECONOMIC BURDEN IN IBD: A
MULTICENTER ITALIAN EXPERIENCE IN PATIENTS TREATED
WITH BIOLOGICS**

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Background

- Inflammatory bowel diseases (IBD), Crohn's disease (CD) and Ulcerative Colitis (UC), are chronic-relapsing inflammatory diseases of the gastrointestinal tract, affecting mainly the young and middle-age, with an increasing incidence worldwide

Lamb CA et al. *Gut* 2019, Loftus EV et al. *Aliment Pharmacol Ther* 2002, Cosnes J et al, *Gastroenterology* 2011

- Despite the enormous progress made in the knowledge of these pathologies and the implementation of our diagnostic armamentarium, over the years it was not possible to reduce the diagnostic delay (DD)

Schoepfer AM et al. *Am J Gastroenterol* 2013, Cantoro L et al. *JCC* 2017

- Diagnostic delay negatively impacts the natural history of disease and affects the patient's quality of life (QoL)

Schoepfer AM et al. *Am J Gastroenterol* 2013, Li Y et al. *Dig Liv Dis* 2015, Schoepfer Am et al. *JCC* 2019, Schoepfer Am et al. *Inflamm Intest Dis* 2021

AIM

Evaluate the diagnostic delay (DD) in patients with IBD and to analyze the clinical burden of the delay in IBD diagnosis in patients treated with biological drugs

In addition, identify the relationship between the diagnostic delay and the quality of life of patients

Materials & Methods

Study population and design

- Multicenter, observational, cross-sectional study (March 2020-March 2023) including IBD adult patients afferent to 19 IBD national hospital and university centers
- Data were obtained from medical patients' records and from a questionnaire administered at inclusion visit, that include:
 - ✓ Personal data
 - ✓ Lifestyle (cigarette smoking, alcohol consumption)
 - ✓ Personal and/or family history of neoplasia
 - ✓ Vaccination status (HBV, HPV, *Pneumococcus*)
 - ✓ Age at diagnosis
 - ✓ UC and CD extension at diagnosis and at study inclusion (according to Montreal Classification)
 - ✓ Disease duration
 - ✓ Extraintestinal manifestations
 - ✓ Data on medical and/or surgical treatment



Materials & Methods

Study population and design

- ***Inclusion criteria:***

- Patients older than 18 years
- Established diagnosis of UC or CD made at least 3 months, based on standard endoscopic, radiology, and histological criteria

Magro F et al. *J Crohns Colitis* 2017, Lichtenstein GR et al. *Am J Gastroenterol* 2018

- Subjects in treatment at the center for at least 1 month, both outpatient and hospitalized

- ***Exclusion criteria:***

- Patients under the age of 18
- Subjects not able to understand and respond to the questionnaires provided by the study
- Patient previously enrolled in randomized clinical trial



Methods

Study population and design

All patients were given, after careful information on the study:

1) **A questionnaire including data on quality of life:**

- hospitalizations in the last year

- working situation: demand for sick leave, problems/difficulties caused by illness in the search for a job, changes of profession/assignment due to pathology

- use in the last 12 months to the gastroenterologist or other medical and non-medical specialists, such as GPs, surgeons, psychologists, nutritionists...

2) **The Quote-IBD questionnaire**, a validated questionnaire to assess the disease-specific quality of care from an IBD patient's perspective

A Important or not? What do you expect from the doctors, nurses and other health care workers?

B) Experiences and problems. What do you actually experience with care services?

Methods

Study population and design

- The institutional review board at each center approved the protocol
- All patients provided written informed consent

Statistical analysis

- Data were reported on Microsoft Excel worksheet
- Statistics was descriptive



RESULTS

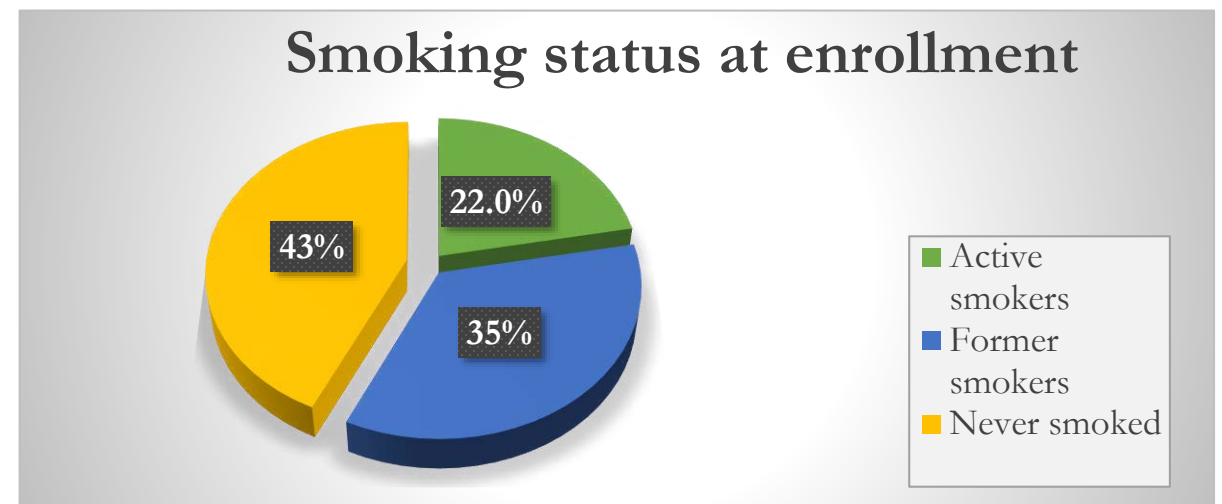
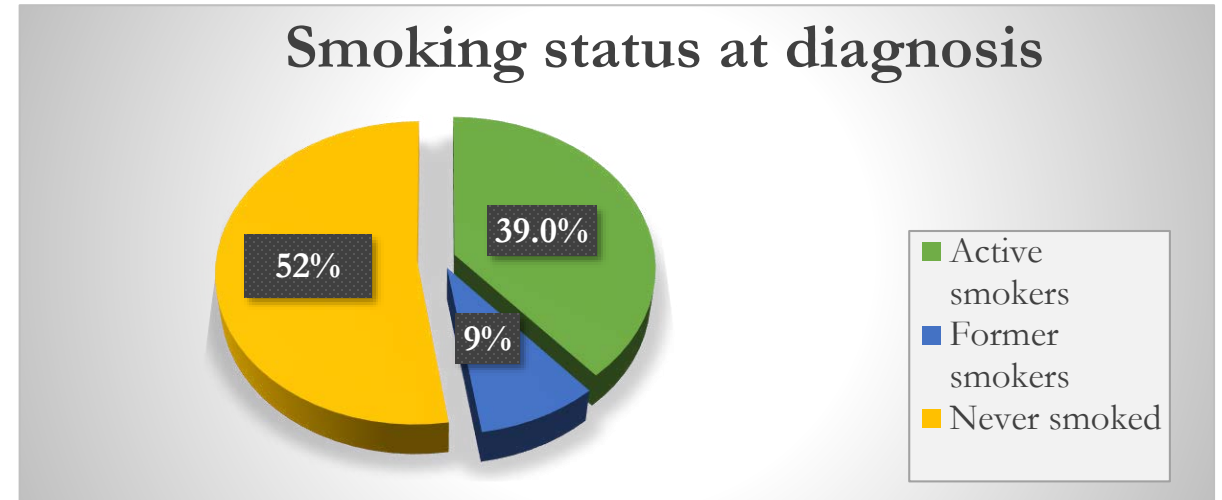


**AIM: to include 500
patients with IBD**

**135 IBD PATIENTS WERE
INCLUDED
(MAR 2020- Mar 2021)**

Demographic and clinical characteristics of the 135 patients enrolled

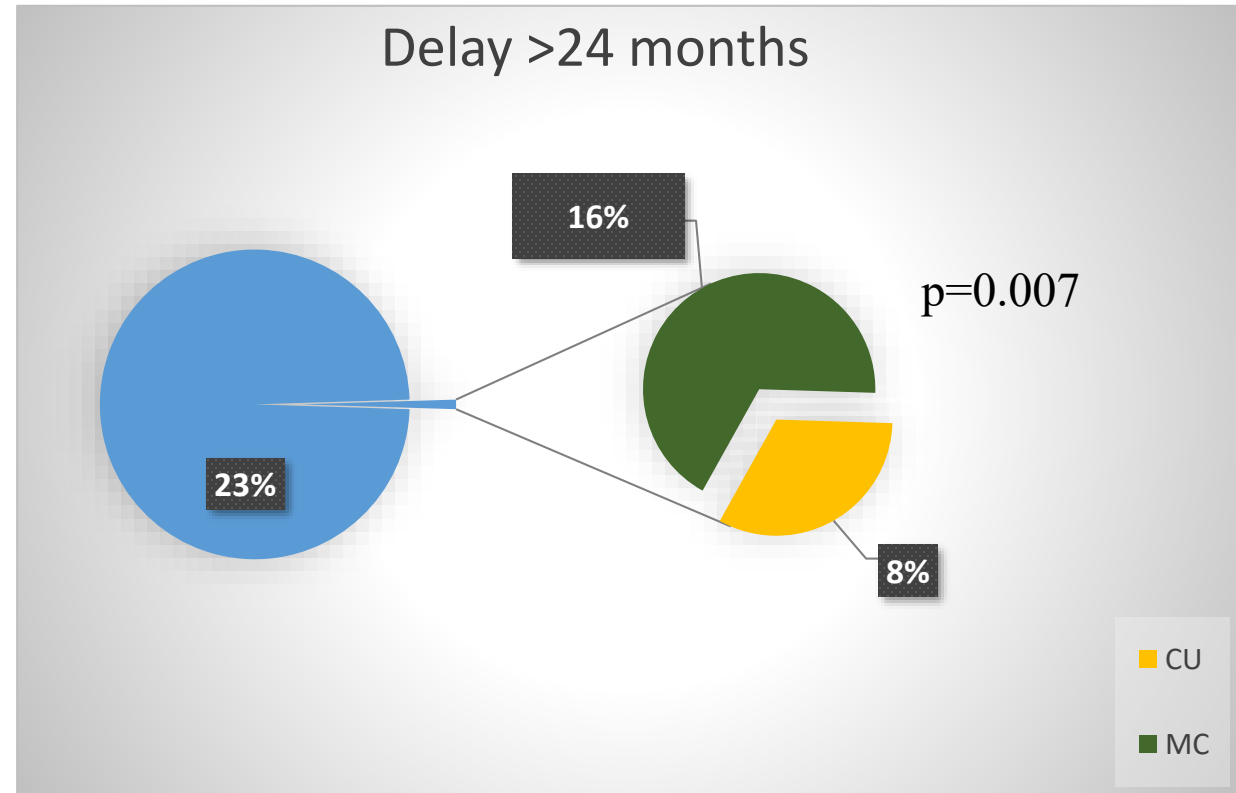
Gender, male (%)	80 (59)
Median (IQR) age, years	47 (34-59)
Median (IQR) age at diagnosis, years	32 (22-45)
Active smokers (%)	30 (22)
Median (IQR) disease duration, years	10 (4-17)
Crohn's disease (CD)	63 (47)
Ulcerative colitis (UC)	72 (53)
Age at diagnosis \leq 40 years	85 (63)
Extraintestinal manifestations at diagnosis	37 (27)
Surgery on enrollment	31/135 (23)
Surgery at diagnosis	11/135 (8)



DIAGNOSTIC DELAY: distribution of all IBD patients

Median (IQR) diagnostic delay	12 months (6-24)
Crohn disease	12 months (IQR: 12-48)
Ulcerative colitis	12 months (IQR: 4.5-12.0)

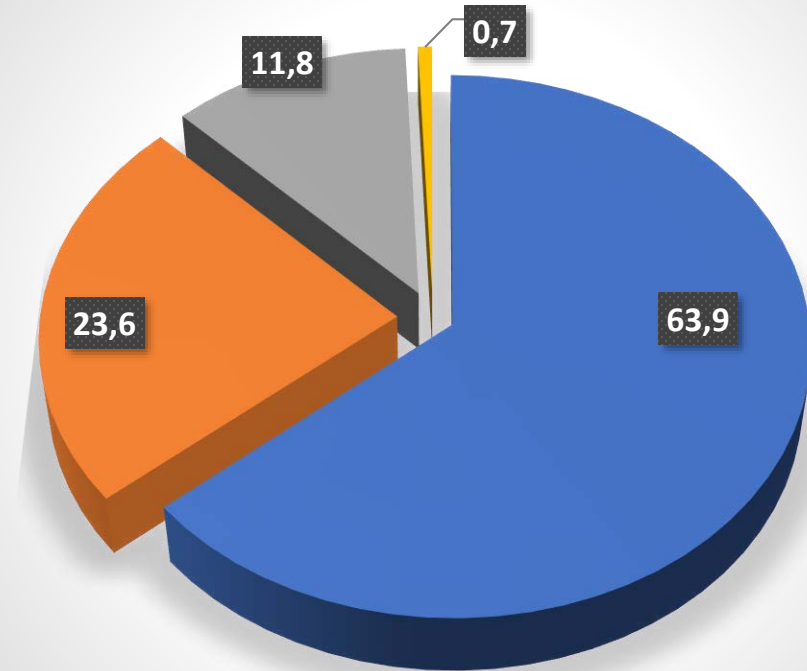
	Diagnostic delay < 24 months n (%)	Diagnostic delay > 24 months n (%)
Tot 135	104 (77%)	31 (23%)
CD 63	42 (31%)	21 (16%)
UC 72	62 (46%)	10 (8%)



BIOLOGICAL THERAPY at enrollment

Median (IQR) disease duration, years 10 (4-17)

% BIOLOGICAL THERAPY ON ENROLLMENT



n135

1°

2°

3°

>4°

63,9%

23,6%

11,8%

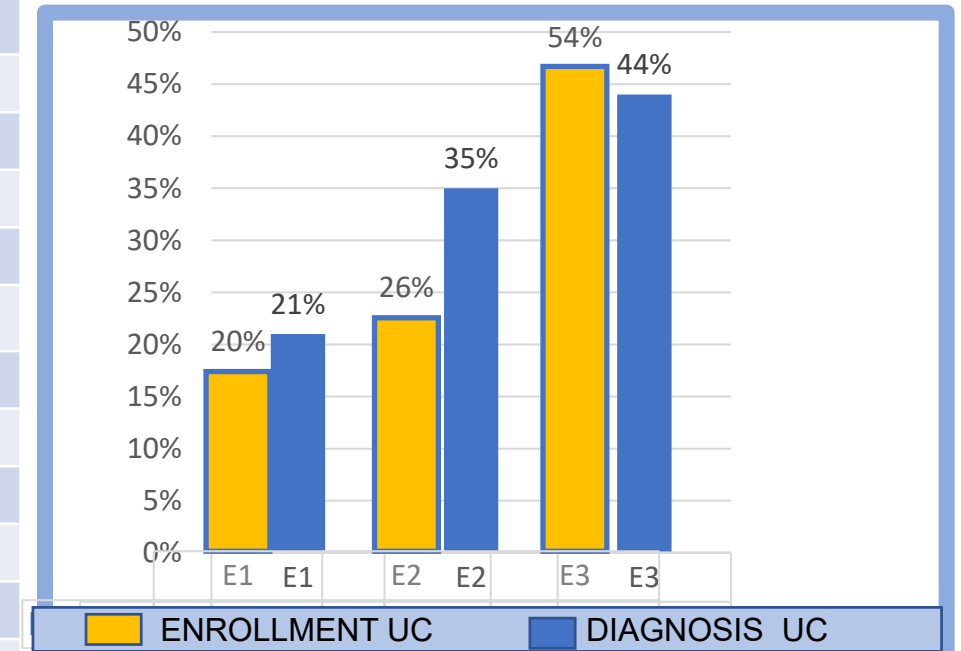
0,7%

DIAGNOSTIC DELAY > 24 MONTHS: statistical analysis

n31			
> 2 biological therapy	4/31	(13%)	p=0.51
≤ 2 biological therapy	27/31	(87%)	
n104 diagnostic delay <24 months			
> 2 biological therapy	15/104	(14%)	
≤ 2 biological therapy	89/104	(86%)	
N31	Surgery		
Yes Surgery	13	(42)	p=0,001
No surgery	18	(58)	
N104 diagnostic delay <24 months			
Yes surgery	20	(19)	
No surgery	84	(81)	

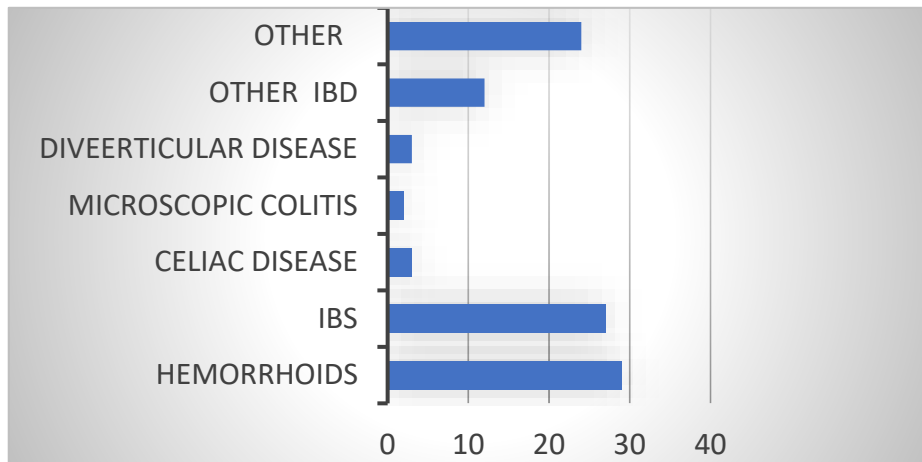
Disease location and phenotype

	DISEASE AT ENROLLMENT N (%)	DISEASE AT DIAGNOSIS N (%)
Crohn's disease n63		
Age		
A1	0	3 (5%)
A2	39 (62%)	41 (65%)
A3	24 (38%)	19 (30%)
Disease location		
L1	25 (39%)	22 (35%)
L2	5 (8%)	11 (17%)
L3	33 (53%)	30 (48%)
Disease behaviour		
B1	42 (67%)	34 (54%)
B2	14 (22%)	24 (38%)
B3	7 (11%)	5 (8%)
Ulcerative colitis n72		
Disease extension		
E1	14 (20%)	15 (21%)
E2	19 (26%)	25 (35%)
E3	39 (54%)	32 (44%)

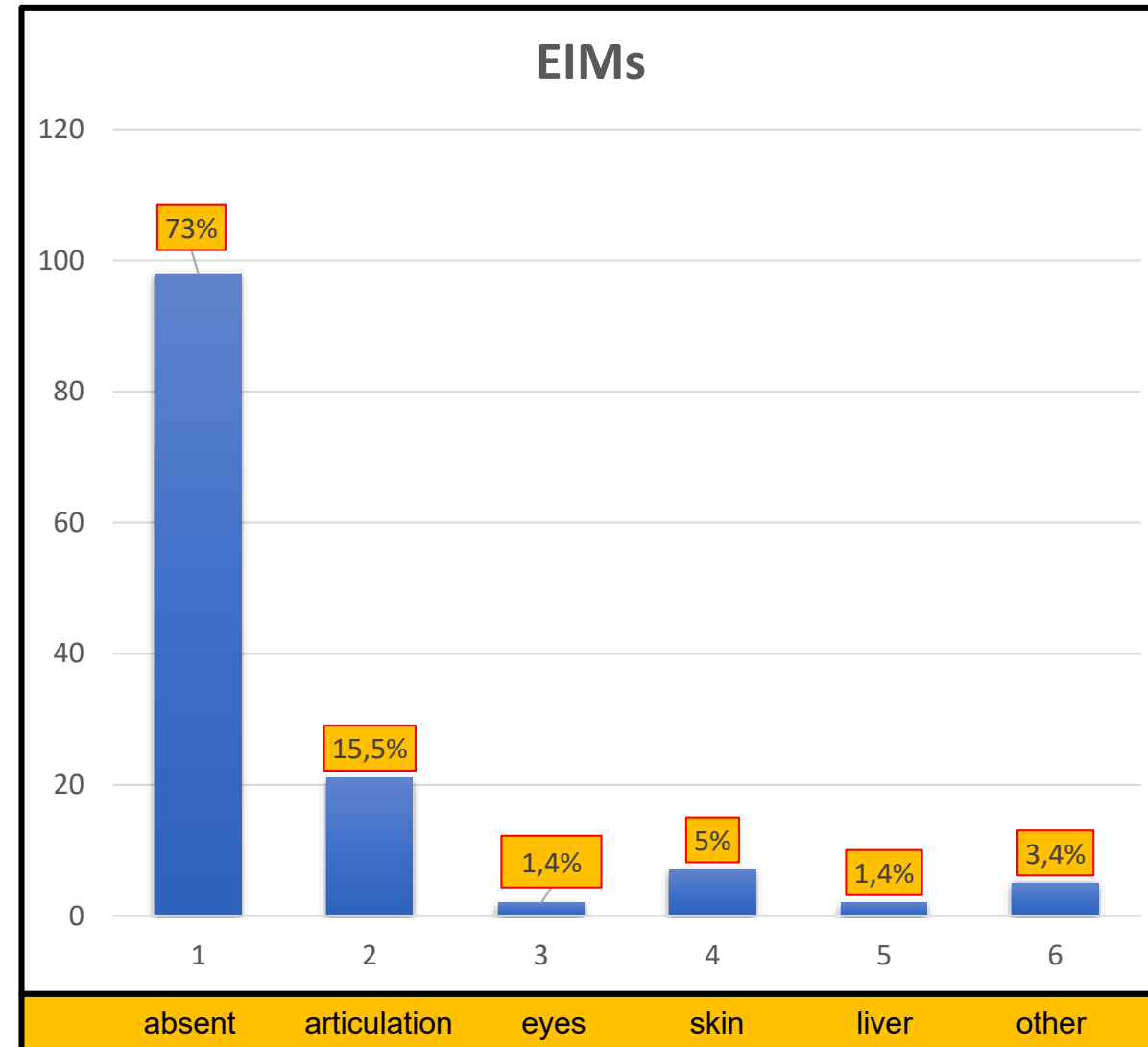


Misdiagnoses of 59/135 IBD patients

	MC	CU	n 59 TOT %
EMORROIDI	3	14	29%
IBS	12	4	27%
COLITE ISCHEMICA	0	0	
MALATTIA CELIACA	2	0	3%
COLITE MICROSCOPICA	1	0	2%
MALATTIA DIVERTICOLARE	1	1	3%
ALTRA VARIANTE MICI	5	2	12%
ALTRO	10	4	24%



EIMS at diagnosis



CONCLUSIONS

- DIAGNOSTIC DELAY REPRESENTS A CRUCIAL CHALLENGE IN THE MANAGEMENT OF IBD, WITH AN IMPORTANT CLINICAL AND THERAPEUTIC IMPACT.
- COLLABORATION WITH THE GASTROENTEROLOGIST SPECIALIST NOT DEDICATED TO IBD AND WITH THE GENERAL MEDICINE DOCTOR IS FUNDAMENTAL, IN ORDER TO REDUCE THE DIAGNOSTIC DELAY AND GUARANTEE PATIENTS AN EARLY AND EFFECTIVE TREATMENT, WITH THE OBJECTIVE OF IMPROVED QUALITY REDUCE THE SOCIO-ECONOMIC BURDEN OF THESE PATHOLOGIES



Grazie