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Impact of Iron-Deficiency Anaemia On Disease Progression In Patients With Inflammatory Bowel Disease: A Real-World Data Analysis In Italy

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Introduction

Inflammatory bowel diseases (IBDs) are chronic inflammatory disorders of the gastrointestinal tract [1]. One of the most common extraintestinal manifestations of IBD is **iron deficiency anaemia** (IDA) [2], which is often an untreated condition that significantly impairs patients' quality of life and elevates mortality and morbidity [3].

Objective

Thus, the aim of the present study was to compare IBD disease progression and healthcare resource utilization in patients with and without a co-diagnosis of IDA in a real-world setting in Italy.

Methods

A **retrospective study** was conducted using Italian entities' administrative databases, covering around 9.3 million health-assisted individuals.

Adult **IBD patients** [with a diagnosis for *Ulcerative colitis* and/or *Crohn's Disease* (identified by at least one hospitalization with ICD-9-CM codes 556, 555 and/or active exemption codes 009.556, 009.555) and/or with prescription for Vedolizumab (ATC code L04AA33)] **were included** between 01/01/2010-30/09/2017 (inclusion period).

Within 12 months from IBD diagnosis, **IDA was identified** by ≥1prescription for iron (ATC code B03A) and/or other anaemia treatments (ATC code B03XA) and/or IDA hospitalization (ICD-9-CM code 280) and/or blood transfusion (proxy of diagnosis, ICD-9-CM code 99.0, primary or secondary procedure, ICD-9-CM code V58.2, primary or secondary diagnosis, specialistic code 99.07.1).

IBD patients were grouped into:

- **IBD patients with IDA** (***IBD-IDA cohort***)
- **IBD patients without IDA** (***IBD cohort***).

The Propensity Score Matching (**PSM**) methodology was applied to abate potential unbalances among the two cohorts. In PSM matched-cohorts, the **IBD disease progression** (defined as the occurrence of IBD-related surgical interventions and hospitalizations), **healthcare resource utilization, and direct costs covered by the Italian National Health System** were assessed during follow-up (12 months).

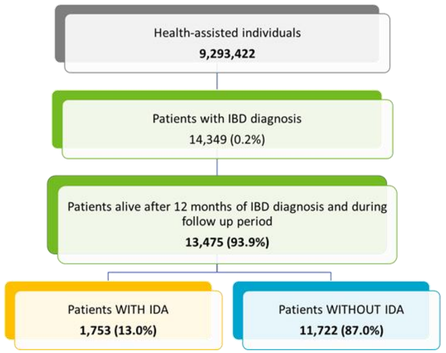
The present study has been approved by the Ethics Committee of each Region/Local Health Units involved in the analysis. The integration of administrative datasets makes it possible to represent the patient's entire clinical history and not just individual prescriptions. The analyses were conducted on exclusively anonymous data in full compliance with privacy regulations. Clicon s.r.l. has obtained the approval as per legislation by all the Ethics Committees to analyse these data. The results are exclusively in aggregated form and never attributable to a single institution, department, doctor, individual, or individual prescribing behaviours. The study was conducted in full compliance with current legislation for retrospective studies.

Results

IDENTIFICATION OF STUDY POPULATION

A total of **14,349 patients with IBD diagnosis** was identified; after excluding those who died in the 12 months after IBD diagnosis date or during follow-up, 13,475 patients were included in the analyses (**Figure 1**): among them **1,753 (13%) formed the IBD-IDA cohort**, **11,722 (87%) the IBD cohort (Figure 1**).

Figure 1. Flowchart of the included patients



IBD PROGRESSION IN IBD AND IBD-IDA PATIENTS

Post-PSM, 5,259 IBD-without-IDA and 1,753 IBD-IDA patients were included in the study (mean age 55 and 56 years, 43% and 44% male, respectively). After PSM, the estimation of **IBD progression** was evaluated by assessing the occurrence of **IBD-related surgical interventions and hospitalizations**.

Table 1. IBD progression during follow- up period, after PSM.

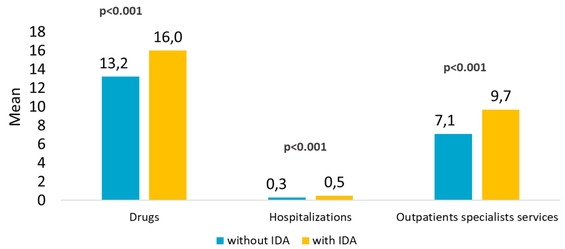
	IBD without IDA		IBD-IDA		
n	5,529		1,753		p
IBD-related surgical interventions (n, %)	104	2.0	53	3.0	=0.01
IBD-related hospitalizations (n, %)	313	6.0	210	12.0	<0.001
IBD progression (n, %)	**357**	**6.8**	**225**	**12.8**	**<0.001**

As reported in **Table 1**, the percentage of IBD-IDA patients with **IBD-related hospitalizations (12%)** and **IBD-related surgeries (3%)** was **significantly higher** than hospitalization and surgery extent found in **IBD-without-IDA** patients (6% and 2%, respectively). The overall IBD progression was significantly higher (P<0.001) in IBD-IDA cohort (12.8%) versus IBD patients (6.8%)

ESTIMATION OF HEALTHCARE RESOURCE CONSUMPTION

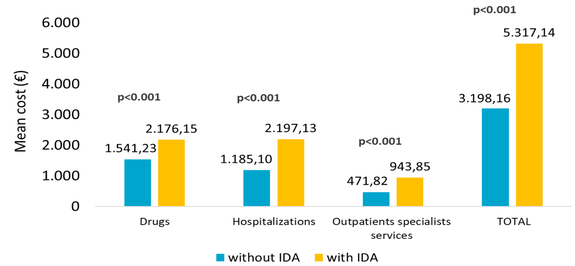
The differences between the two cohorts were also evaluated in terms of healthcare resource consumption and costs during follow-up. As reported in **Figure 2**, the average **annual healthcare number of resource utilization** per patient in terms of drug prescriptions (16 vs. 13.2), hospitalizations (0.5 vs. 0.3), and outpatients specialist services (9.7 vs. 7.1) was **significantly increased in IBD-IDA versus IBD-without-IDA patients.**

Figure 2. Mean annual number of healthcare resources during follow up period, post PSM



Costs were found to be **higher among IDA patients** (p< 0.001), with an overall mean annual cost of **€5,317** compared to **€ 3,198** of patients without IDA (**Figure 3**).

Figure 3. Mean annual annual costs during follow up period, post PSM



Conclusion

The results of this **real-life analysis** have depicted the occurrence of IDA among patients affected by IBD in Italy. Almost 13% of IBD identified patients had a co-diagnosis of IDA. The presence of IDA in these patients might result in the worst disease progression, as indicated by the increase of IBD-related surgical interventions and hospitalization. In addition, IDA co-diagnosis was associated with higher healthcare resource utilization and higher cost. In conclusion, since the anemic state in IBD patients is related to a decreased quality of life and many comorbidities [3,4], it should be considered for the therapeutic management of these patients.

References

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